COMPARATIVE STUDY OF MODIFIED RANDALL-TENNISON'S REPAIR AND FISHER'S ANATOMICAL SUBUNIT REPAIR IN UNILATERAL CLEFT LIP PATIENTS

A THESIS SUBMITTED TO BABA FARID UNIVERSITY OF

HEALTH SCIENCES, FARIDKOT (PUNJAB)

IN THE PARTIAL FULFILLMENT

FOR THE AWARD OF DEGREE OF

M.Ch

IN

PLASTIC & RECONSTRUCTIVE SURGERY

MAY, 2023

Submitted By

DR. SUMIT SINGH GAUTAM

DEPARTMENT OF PLASTIC & RECONSTRUCTIVE SURGERY
DAYANAND MEDICAL COLLEGE AND HOSPITAL
LUDHIANA, PUNJAB

DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled **"COMPARATIVE STUDY OF MODIFIED RANDALL-TENNISON'S REPAIR AND FISHER'S ANATOMICAL SUBUNIT REPAIR IN UNILATERAL CLEFT LIP PATIENTS"** submitted towards partial fulfillment of the requirements for the award of **M.Ch** in **PLASTIC & RECONSTRUCTIVE SURGERY** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Ramneesh Garg,** Professor, Department of Plastic surgery, **Dr. Rajinder Mittal**, Professor & Head, Department of Plastic surgery. No part of this thesis has formed the basis for the award of any degree previously.

_____

DR. SUMIT SINGH GAUTAM
Department of Plastic & Reconstructive Surgery
Dayanand Medical College & Hospital,
Ludhiana, Punjab

Date:

Place:

CERTIFICATE OF SUPERVISORS

This is to certify that the work incorporated in this thesis entitled **"COMPARATIVE STUDY OF MODIFIED RANDALL-TENNISON'S REPAIR AND FISHER'S ANATOMICAL SUBUNIT REPAIR IN UNILATERAL CLEFT LIP PATIENTS"** has been carried out by **Dr. Sumit Singh Gautam** under our direct supervision. The data incorporated in this thesis is original and genuine and has been carried out by the candidate himself.

Signature of Supervisor

Dr. Ramneesh Garg
Professor
Department of Plastic Surgery
DMCH, Ludhiana

Signature of Co-Supervisor

Dr. Rajinder Mittal
Professor& Head
Department of Plastic Surgery
DMCH, Ludhiana

Date:

ENDORSEMENT BY THE HEAD OF THE INSTITUTE

This is to certify that the thesis entitled **"COMPARATIVE STUDY OF MODIFIED RANDALL-TENNISON'S REPAIR AND FISHER'S ANATOMICAL SUBUNIT REPAIR IN UNILATERAL CLEFT LIP PATIENTS"** is a bonafide research work done by **Dr. Sumit Singh Gautam** under the supervision of **Dr. Ramneesh Garg,** Professor, Department of Plastic surgery, **Dr. Rajinder Mittal**, Professor & Head, Department of Plastic surgery, in this institution.

Principal

Dr. Sandeep Puri
Principal
DMC&H, Ludhiana

Date:

COPYRIGHT

Declaration by the Candidate

I hereby declare that the Baba Farid University of Heath Sciences, Faridkot, shall have the rights to preserve & use this thesis in print or electronic format for academic/study purpose by the research scholar/students.

Signature

Dr. Sumit Singh Gautam
Department of Plastic & Reconstructive Surgery
Dayanand Medical College & Hospital,
Ludhiana, Punjab

Date:

© Baba Farid University of Health Sciences, Faridkot

Dedicated

to

my family

&

Teachers

ACKNOWLEDGEMENT

I would like to express my sincere gratitude to the following individuals who have provided exceptional support and guidance throughout my thesis journey:

First and foremost, I extend my heartfelt appreciation to Dr. Ramneesh Garg, my esteemed guide and chief for this thesis. Your meticulous approach, unwavering support, and belief in my abilities have been transformative. Your guidance has not only shaped my thesis but also played a crucial role in boosting my confidence and competence as a plastic surgeon. Your dedication to excellence and faith in me have been truly inspiring.

I would also like to express my deep gratitude to Dr. R.K. Mittal, for your insightful contributions and simplistic approach to matters. Your ability to distill complex subjects into clear and understandable concepts has been invaluable. Your guidance has influenced my overall approach to work, enhancing my understanding and improving my skills as a surgeon.

Dr. Sheerin Shah, I am immensely grateful for your tremendous support in my professional work and overall development as a plastic surgeon. Your guidance, expertise, and mentorship have shaped the surgeon I aspire to be. Your contributions and insights have broadened my perspective and enriched my knowledge in the field of Plastic and Reconstructive Surgery.

To my dearest wife, Dr. Reva Tyagi, your support, patience, and understanding throughout this demanding

journey have been priceless. Your love, encouragement, and belief in my abilities have been my constant source of strength. Your sacrifices and unwavering faith in me have made this achievement possible. I feel blessed by the happiness and motivation that our beloved son, Ved, adds to our existence.

I would like to extend my heartfelt appreciation to my parents for their unending support, encouragement, and belief in me. Your love, guidance, and sacrifices have been instrumental in shaping my academic and professional journey. I am forever grateful for your support and the values you instilled in me.

I would also like to acknowledge the contributions of Dr. Bhavuk Jaiswal and Dr. Renu Verma for their valuable discussions and camaraderie, which have contributed to my growth as a surgeon.

Finally, I would like to acknowledge the contributions of Dr. Ojassvi and Dr. Deepika, my juniors. I am grateful for the fruitful discussions, collaboration, and mutual learning experiences we shared.

To all those who have directly or indirectly contributed to my thesis and my growth as a surgeon, I express my heartfelt appreciation. Your support, encouragement, and belief in my abilities have been instrumental in the successful completion of this work.

Dr. Sumit Singh Gautam

LIST OF ABBREVIATIONS

FAS	**-**	Fisher's anatomical repair
MRT	**-**	Modified Randall-Tennison repair

ABSTRACT

Background: This study aimed to compare the aesthetic outcomes of Fisher's Anatomical Subunit repair and Modified Randall-Tennison repair in cleft lip surgery.

Objective: The aim of this study was to assess and compare the aesthetic outcomes of Fisher's Anatomical Subunit repair and Modified Randall-Tennison repair in patients undergoing unilateral cleft lip surgery.

Methods: A prospective study was conducted involving 40 patients who were divided into two groups: Group A (Modified Randall-Tennison repair) and Group B (Fisher's Anatomical Subunit repair). Aesthetic outcomes were evaluated using the Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL-SOE) scale. Demographic analysis was performed to assess age and sex distribution.

Results: Fisher's Anatomical Subunit repair showed significantly higher scores for nasal symmetry compared to Modified Randall-Tennison repair ($p = 0.015$). However, no significant differences were found for other aesthetic parameters, including Cupid's bow symmetry, lateral lip symmetry, and free vermillion symmetry. The average and total UCL-SOE score also revealed higher scores in Fisher's Anatomical Subunit repair ($p < 0.05$).

Conclusions: Fisher's Anatomical Subunit repair yielded superior aesthetic outcomes, particularly in nasal symmetry, compared to Modified Randall-Tennison repair in cleft lip surgery. These findings highlight the importance of considering the surgical technique when aiming for optimal aesthetic results. Further research is warranted to validate these findings and explore additional factors influencing aesthetic outcomes in cleft lip surgery.

Key words: Cleft lip, aesthetic outcomes, Fisher's Anatomical Subunit repair, Modified Randall-Tennison repair, UCL-SOE scale.

TABLE OF CONTENTS

S.NO.	TOPIC	PAGES
I	INTRODUCTION	1-3
II	AIMS AND OBJECTIVES	4
III	REVIEW OF LITERATURE	5-16
IV	MATERIALS AND METHODS	17-22
V	OBSERVATIONS AND RESULTS	23-34
VI	DISCUSSION	35-39
VII	SUMMARY AND CONCLUSIONS	40
VIII	BIBLIOGRAPHY	41-45

APPENDICES–I

- PROFORMA
- MASTER CHART

APPENDICES–II

- APPROVAL LETTER OF THESIS PLAN
- THESIS PLAN

LIST OF TABLES

TABLE NO.	TITLE	PAGE NO.
1.	Age distribution	24
2.a.	Age distribution in Group A	25
2.b.	Age distribution in Group B	25
3.	Gender distribution	26
4.a.	Gender distribution in Group A	26
4.b.	Sex distribution in Group B	26
5.	Comparison of mean scores for UCL-SOE scale between the two groups using evaluation by a surgeon	27
6.	Comparison of mean scores for UCL-SOE scale between the two groups using evaluation by a nurse	29
7.	Comparison of mean scores for UCL-SOE scale between the two groups using average score of the two evaluators	32

LIST OF FIGURES

FIGURE NO.	TITLE	PAGE NO.
1	Abnormal attachment of Orbicularis Oris muscle	5
2	Straight Line Repair	8
3	Tennison Repair	8
4	Randall-Tennison Repair	10
5	Millard's Rotational Advancement Repair	11
6	Fisher's Anatomical Subunit Repair	13
7	Evaluation via UCL-SOE Scale	18
8	Scoring via UCL-SOE scale	19
9	Age distribution (In Months)	24
10.a.	Age Distribution Group A	25
10.b.	Age Distribution Group B	25
11	Gender Distribution	26
12.a.	Sex Distribution (Group A)	26
12.b.	Sex Distribution (Group B)	26
13	UCL-SOE scoring by the Surgeon Evaluator	28
14	UCL-SOE scoring by the Nurse Evaluator	30
15	Total UCL-SOE Score for each group comparing 2 evaluators	31
16	Scores by the two evaluators - compared	33
17	Average UCL-SOE Scoring	33
18	Average Total Score	34

LIST OF PICTURES

PICTURE NO.	TITLE
	Fisher's Anatomical Subunit Repair
1	Pre-op photograph – Frontal
2	Pre op – Basal
3	Markings for Fisher's Anatomical Subunit Repair
4	Post op – Frontal – Fisher's Anatomical subunit Repair
5	Post op – Basal – Fisher's Anatomical Subunit Repair
	Modified Randall-Tennison's Repair
6	Pre-op Frontal
7	Pre-op Basal
8	Post-op Frontal
9	Post op Basal

INTRODUCTION

Cleft lip, a congenital malformation where the upper lip fails to fuse during fetal development, is a prevalent birth defect that affects approximately 1 in every 1000 live births globally.[1] This condition has been extensively researched and documented across numerous academic disciplines worldwide. In India, out of the 24.5 million births per year, the birth prevalence of clefts is somewhere between 27,000 and 33,000 clefts per year.[2]

The unilateral cleft lip deformity presents with a paucity of tissue between the nasal sill superiorly and the lip inferiorly. It involves a full-thickness defect of the lip (and possibly the alveolar ridge and palate), from the base of the nose to the free margin of the oral cavity. The underlying palatal shelves may be similarly clefted and malpositioned, contributing to the deformity.

Numerous techniques have been defined for the aesthetic outcome of a cleft lip repair. Repair involves anatomic re-creation of the lip elements on the uninvolved side of the lip.The main idea of all these techniques is the precise dissection of the orbicularis oris pathological muscle insertions around the cleft, and their reinsertion into the correct anatomical position, to reconstruct the normal nasolabial anatomy.[3] The goals of unilateral cleft lip repair are both functional and aesthetic. Aesthetically the goals of surgical intervention include formation of lip continuity, establishing symmetry of the cupid's bow and the nose in a manner that places scars in less discernible areas.

Mulliken, in 1985, established the following fivesurgical principles for the repair of cleft lip[4]:

1) maintain symmetry,
2) secure primary muscle union,
3) select proper prolabial size and configuration,

4) Form the median tubercle and mucocutaneous ridge from lateral lip tissue, and
5) Construct the nasal tip and columella by anatomic placement of the alar cartilages.

Keeping these principles as the standard, various techniques of lip repair have been described, each of which position the cutaneous scar uniquely. Innumerable techniques have been in use, but the most popular are Randall-Tennison repair and Millard's rotation advancement repair.

Among the recently introduced techniques, the one that follows the concept of anatomical subunit repair is the Fisher's repair.

Introduced in 2005, Fisher's[5] anatomical subunit approximation technique that combines several previous repair methods and follows the concept of anatomical lip subunits. This approach seeks to create a cutaneous scar in alignment with the optimal line of repair for better anatomical subunit restoration.

Additionally, assessment of the aesthetic outcome of unilateral cleft lip repair has been a topic of interest for many researchers.Researchers have created and tested scales, but proposed methods vary widely in their study design, patient population, treatment stage, type of cleft, evaluators' education, and familiarity with the patients and techniques.

Multiple outcomes scales such as those given by Johnson et al.[6], Kim et al.[7], Sitzman et al.[8] were introduced which included late post op esthetical evaluation parameters. Finally, the Asher-McDade[9] index measures four parameters during late postoperative stages such as nasolabial profile, nasal deviation, nasal form and vermillion border to evaluate surgical results effectively.

Different study groups have utilized different parameters, however there is a lack of a standardized scoring system which can be utilized by even a layman. Unilateral Cleft Lip Surgical Outcomes Evaluation

(UCL SOE) Scale[10] is one such scale which allows analysis of photographs taken in immediate post procedure intra operative period. The UCL SOE scores symmetry of 4 individual anthropomorphic components of the cleft repair (Cupid's bow, lateral lip, nose, and free vermillion).

There are no exclusive studies comparing aesthetic outcomes based on Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale. Therefore, the purpose of this study is to compare the aesthetic outcomes for patients with unilateral cleft lip undergoing Modified Randall-Tennison's repair or Fisher's anatomical subunit repair.

The variability of outcomes achieved using different techniques highlights the need for further research into which technique is most effective in achieving optimal aesthetic results in unilateral cleft lip repair. Thus, this study aims to contribute to the available literature on cleft lip repair by comparing the aesthetic outcomes of Modified Randall-Tennison's repair and Fisher's anatomical subunit repair techniques using the UCL SOE Scale, with the hope of providing insights into which technique may be more effective in achieving superior aesthetic outcomes for patients with unilateral cleft lip.

AIM AND OBJECTIVE

To compare the aesthetic outcome of unilateral cleft lip repair between Modified Randall-Tennison's Repair And Fisher's anatomical subunit repair on the basis of Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale

REVIEW OF LITERATURE

Surgical management of cleft lip involves a methodical approach that requires precise identification of the involved structures and meticulous attention to detail in reconstructive techniques. Various surgical techniques have been developed for the repair of cleft lip, ranging from traditional methods such as the straight-line repair, Randall-Tennison triangular flap repair, Millard rotation-advancement repair to more advanced techniques like the Fisher's anatomical subunit repair. The unilateral cleft typically results in a disruption of cupid's bow and the absence of one philtral column. The continuity of the orbicularis oris circumferentially is compromised, with abnormal insertions. In the lateral lip element, the upper part of cutaneous orbicularis (Pars Superficialis) inserts in the lateral aspect of the alar base and the nasolabial fold, while the lower part inserts into the nostril base periosteum of the pyriform rim. In the medial lip element, the cutaneous orbicularis (pars superficialis) inserts into the anterior nasal spine and columella. The deep orbicularis (pars marginalis) is simply interrupted by the cleft deficiency and results in a diminished vermillion-cutaneous ridge at the cleft margin.[6]

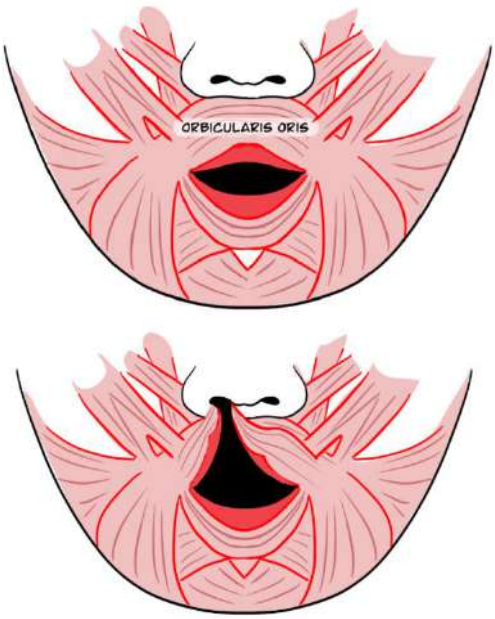


Figure 1 a: Abnormal attachment of Orbicularis Oris muscle

The goals of unilateral cleft lip repair are both functional and aesthetic. To address these goals, one must understand the anatomical characteristics of unilateral cleft lip. Aesthetically the goals of surgical intervention include formation of lip continuity, establishing symmetry of the cupid's bow and the nose in a manner that places scars in less discernable areas. Recreation of the orbicularis muscle to circumferentially surround the opening of the oral cavity is important for long-lasting cosmetic outcomes and lip and mouth function.

The ideal goals of cleft lip repair include[11]:

- Achieving approximation of the medial and lateral lip elements without losing natural landmarks.

- Thoughtful removal of tissue to excise poor quality cleft marginal tissues and achieve a balanced lip.

- Placing the scar of union along natural lines, considering the anatomical subunits of the lip-nose complex.

- Repairing the muscle.

- Ensuring equal circumference of the nostril margins and symmetric alar bases from the anterior view.

Outline of historical surgical aspects

The Chin Annals of China documented the first-ever cleft lip operation in 390 AD[12]. During this period, surgery was performed by simply cutting and aligning the cleft edges. AmbroiseParé is credited with outlining a technique that involved freshening of the cleft edge while holding the ends closely together using a needle threaded with figure-of-eight thread. The earliest closures were straight-line approaches such as those developed by Rose[13] and Thompson[14]. In 1844, Mirault[15] was believed to be among the pioneering users of lower lip flap from its lateral segment across the base part of harelip; however, Blair[16] and Brown[17] modified it during their operations in 1945 resulting into simple repair without Cupid's bow shape formation. An

alternative triangular flap design through lateral lips similar to Hagedorn[18] approach was used earlier by Jalaguier[19] back then but enhanced methodology establishing Cupid's bow structure via application on quadrilateral flaps at a higher level distinguished Hagerdon from others long ago thereafter.

A significant development in cleft surgery was the identification of Cupid's bow in the cleft lip. This led Arthur Baker Le Mesurier[20] to modify Hagerdon's technique, followed by C.W. Tennison[21] who introduced a more advanced repair method for retaining and positioning Cupid's bow, a technique which was modified and popularized by Randall[22]. Millard[23] gained popularity with his rotation-advancement approach presented first in 1955 then modified in 1958, which is now one of two widely used methods alongside Tennison's iterative procedure with numerous alterations over time. The transformation from Millard's early demonstration to recent ones published between 1957 to 1999 reflected evolution and iteration for over a half-century career spanned lifetime innovation progression.

Straight line repairs

Early surgical techniques in treatment of cleft lip deformity involved straight-line repairs were limited in restoring symmetry to the lip of a child with unilateral cleft lip. Straight line techniques have the potential for scar contracture with consequent shortening of the lip, as excess normal tissue along the cleft margins is sacrificed to achieve straightline closure and the shape of Cupid's bow is blunted.[24]

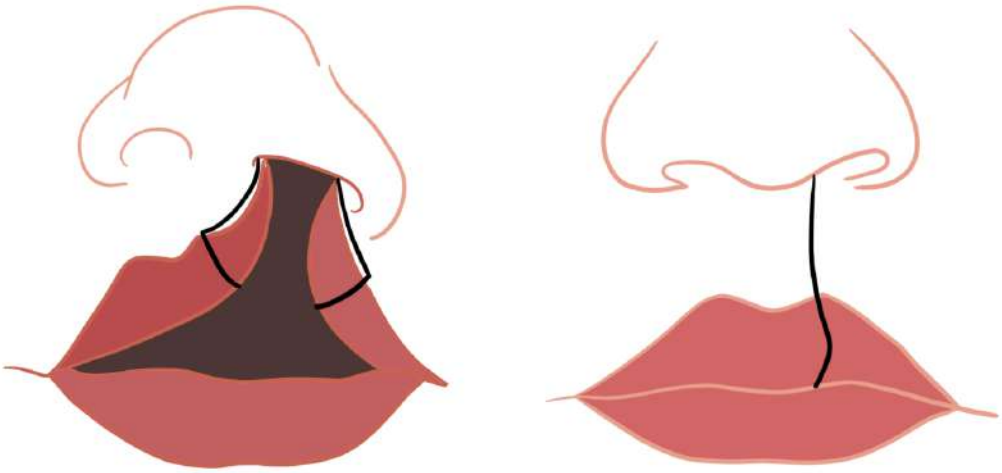


Figure 2: Straight Line Repair

Tennison repair (1950)

These shortcomings have led to the use of geometrically designed flaps. Theoretical advantages of geometric techniques include applicability to a wide range of cleft sizes, the ability to symmetrically recreate Cupid's bow, achievement of adequate rotation and lip length, increased fullness of the philtral tubercle, and minimal wasted tissue.[25,26]LeMesurier and Tennison[21] developed the use of flaps that allowed reconstruction of the cupid's bow of the lip. Tennnison applied the use of a 'Z' shaped metal wire to imprint on the skin of the lateral lip element on the cleft side to act as additional tissue being used to create the upper lip element.

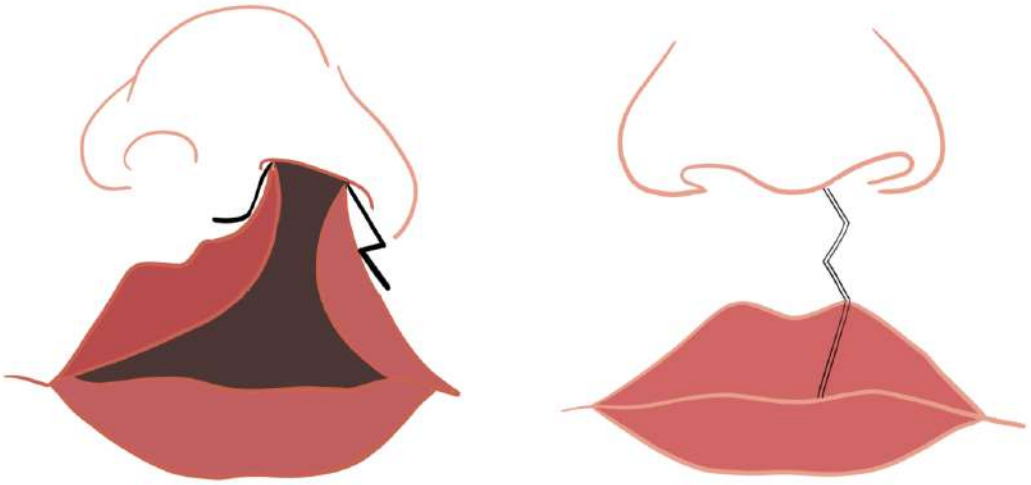


Figure 3: Tennison Repair

Randall’s modification of Tennison’s repair

Randall, in 1959, utilized this triangular-shaped flap to make a more methodological approach to the repair of unilateral cleft lip. He employed using precise measurements to mark the size of the triangular flap required to gain height in the upper lip and to recreate symmetry.

The Z-plasty technique known as the inferior triangle repair involves sharing the middle limb of the Z between incised cleft margins. In order to produce a zigzag scar with equal limbs, Tennison utilized a bent wire stencil, whereas Randall employed callipers and basic mathematical principles to adjust both length and size of the inferior triangle. During this particular method, measurement is taken from a reference point in nostril sill to non-cleft side peak of Cupid's bow for total lip height on that side. On cleft side, greater lip height is measured from proposed medial point at nostril sill level (symmetric with non-cleft-side nostril sill reference) up to peak of Cupid's bow. The difference between total lip height and greater lip height approximates lesser height while also determining base width required for levelling Cupid’s bow within inferior triangle dimensions. The utilization of inferior triangle repair presents numerous benefits. Simple medial and lateral nostril sill element approximation is effective in achieving closure of the nostril sill, resulting in minimal scarring at the nasal base. Even when there is a limited height to the medial lip, successful achievement of lip length can still be attained. Moreover, where there may exist shortness in lateral lip height as commonly seen with complete clefts, this technique allows for its accomplishment without compromising Noordhoff's point. However, one drawback includes an uncharacteristic zigzag scar formation; furthermore, secondary revisions may pose difficulties given that Z-plasty lies within the middle region of the lip.

Due to this, rather mathematical approach, the technique has gained popularity among young surgeons who find the technique easily reproducible and reliable in terms of achieving consistent results.

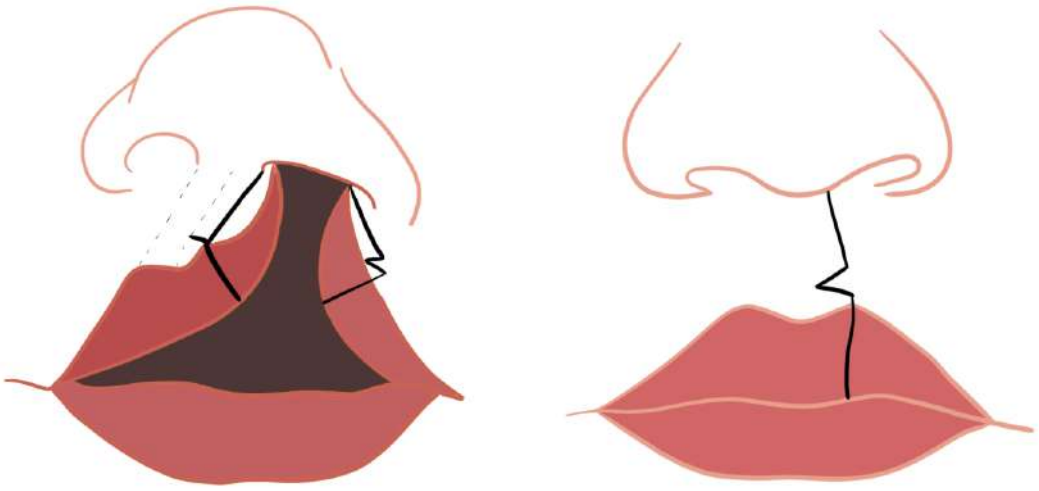


Figure 4: Randall-Tennison Repair

Millard’s Rotational Advancement Flap

Millard's technique[27]of “rotation-advancement” brought about the modern era of cleft lip reconstruction. Millard's rotation-advancement repair involves a curved incision on the medial lip element. The curvilinear cut follows the non-cleft side philtral column in its lower half and extends along the crease of the lip columella but should not intersect with said column. This maneuver allows for downward rotation of Cupid's bow apex on cleft sides while utilizing a triangular flap from lateral elements to cover resultant defects. A "c-flap" is formed by rotating prolabial skin laterally to aid nostril sill closure; however, Millard noted that inadequate rotations may necessitate back-cutting from cranial extreme down medial lips proximal to noncleft side philtral columns. To level Cupid's bow, the back-cut is extended caudally and then filled with a c-flap to elongate the columella on the cleft side. Preserving both Cupid's bow and philtral dimple, this repair presents an advantage where scars in the lower lip mirror non-cleft-side philtral columns. However, there are some drawbacks to this technique such as excessive scarring at columellar base, nostril sill, and alar crease which can cause nostril stenosis if used to close it. Additionally, while anatomical mirror imaging of upper lip philtral column is not achieved through this method. The cut-as-you-go execution of this approach remains favored by many surgeons despite its limitations. According to

some opinions, the medial and lateral aspects of the nostril sill exist in their original state without any need for augmentation from lip skin. The use of a c-flap is believed to interfere with the natural roll of the nostril sill. Additionally, performing an extensive incision around the base of the nose can result in a noticeable scar and therefore has been abandoned by many surgeons as unnecessary. In order for successful repair, it is necessary that there be sufficient length for both cleft marginal and rotation incisions such that they meet at full length; otherwise, extension beyond Noordhoff's point may be required resulting in further compromise to already short transverse lengths.

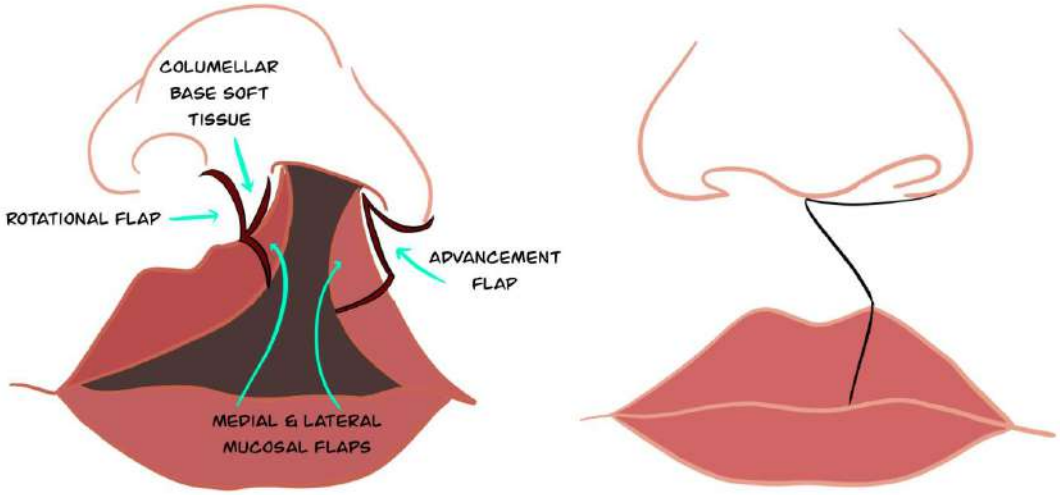


Figure 5: Millard's Rotational Advancement Repair

Mohler modified the rotation-advancement repair procedure in order to create a scar that is more evenly balanced with the non-cleft-side philtral column. This was accomplished by adjusting the curve of the rotation incision and extending it into the columella, whereupon a back-cut was made at a right angle before finishing at the lip columellar crease. The resulting transverse limb of this altered version reaches up to meet with the lip-nose junction, which is considered an improvement over its original counterpart. Mohler asserts that taking tissue from within the columella proves relatively innocuous; however, Noordhoff cautions against employing such methods when dealing with narrow columellas as it may be contraindicated for use under these circumstances.

The repair method presents a distinct benefit over Millard's rotation-advancement technique, as it yields an anatomically positioned scar. Nonetheless, similar to all other approaches utilizing rotation-advancement procedures, the methodology involves sacrificing transverse lateral lip length in cases where vertical shortness of the lateral lip exists.

Later refinements by Salyer, Noordhoff, Cutting, and others have allowed the surgeon to more effectively restore function, symmetry, and aesthetics.

Fisher's Anatomical Subunit Repair

Fisher described a hybrid technique in 2005 that is termed the anatomical subunit approximation technique.[5] The process refers to diverse antecedent repair procedures and abides by the notion of anatomical lip subunits.

Fisher proposed a technique for anatomical subunit repair that is aimed at creating a cutaneous scar along the "ideal line of repair." This involves ascending the lip above the roll along a line drawn to mimic the philtral column on the noncleft side and then curving superolaterally along the lip columellar crease until closure in nostril sill. Lip lengthening is achieved through two mechanisms, including Rose-Thompson lengthening and positioning of a small triangle above the roll if medial lip height deficiency exists, which occurs more frequently than not.

The Rose-Thompson effect must be taken into account when determining the necessary height of the inferior triangle, as it is capable of achieving approximately 1 mm lengthening. In addition to incorporating Noordhoff's vermilion triangle in the repair process, Fisher developed an anatomical subunit repair method which he utilizes for all unilateral cleft lip repairs due to its various advantages. These include minimal scarring at the base of the nose and uninterrupted closure of nostril sills. The scar runs along seams between anatomical subunits with only a small triangular area above

the roll requiring separate attention if needed. Tension is optimally positioned above this roll element with continuity being achieved through side-to-side approximation methods while preserving lateral lip transverse length without sacrificing vertical height attainment.

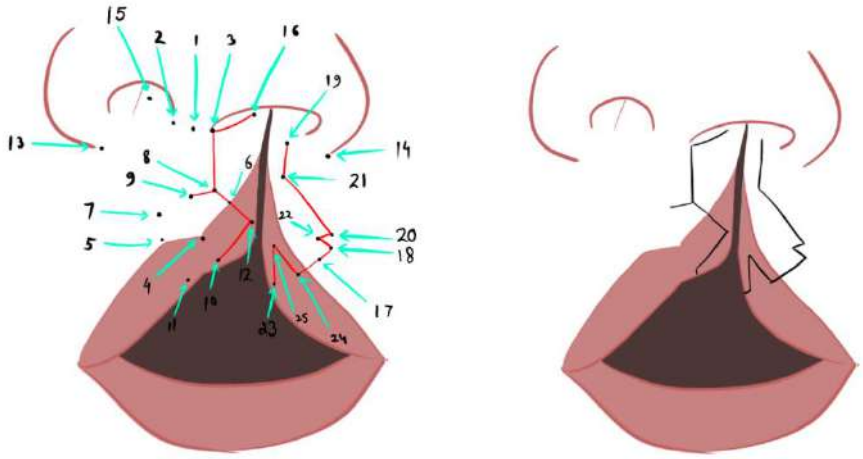


Figure 6: Fisher's Anatomical Subunit Repair

The ideal operation for repair of a unilateral cleft lip should result in a symmetrical upper lip with equal philtral column length on either side. The scar should mirror the opposite side and should not transgress the philtral column. There should also be no peaking at Cupid's bow at the cleft side or notching of the vermillion. In addition, Cupid's bow should be of adequate proportions.[28]Christofides and others opined that these criteria should be obtainable in a single operation without multiple minor revisional procedures.[29]

Of the various surgical techniques reviewed for unilateral cleft lip repair, Fisher's anatomical subunit approximation technique is one that allows maximum respect of the philtrum while minimizing columella scar formation. Fisher's repair method was inspired by anatomical subunit concepts proposed by Gonzalez-Ulloa[30] et al in 1954 and Burget and Menick[31] in 1985, with the design considering each anatomical subunit and attempting to place closure lines along their borders. The Fisher technique has been shown to yield favorable results with a low rate of complications, including minimal scarring and distortion.

Assessment of surgical outcome

Assessment of the appearance of the cleft-related deformity and the impact of surgical treatment is a critical component of the quality of life outcome for this patient pool.[32] Nasolabial appearance is, arguably, one of the most important measures of the success of treatment for unilateral cleft lip.[9]

Methods to assess nasolabial appearance can be broadly divided into qualitative and quantitative methods. The latter methods aim to analyze the extent of abnormal morphology and the degree of disproportion objectively through facial measurements.[33] Qualitative methods are more subjective and involve analyses of facial aesthetic and appearance impairment using scales, indices, scoring systems, and rankings. Subjective assessment of appearance and aesthetics is fraught with difficulty, but is most likely to reflect the patient's and general public's perception of facial impairment.[6]

Friede et al, in 1980 took plaster casts of the mid face, analysing angular, linear and surface measurements in 30 patients, 4-10 years post-procedure. This allowed objective quantification of the dimensions, however the process was cumbersome and could have compliance issues.

Assuncau[34]**,** in 1992, devised the V.L.S. classification for secondary deformities in unilateral cleft lip patients, separating the lip into 3 sections - the vermilion, lip, and scar. However, he did not define any rationale for choosing these landmarks, nor did it include he evaluation of the nose.

Johnson N et al devised an aesthetic index for evaluation of cleft repair which was proven reproducible.[6]This index evaluated late post op outcomes. Kim et al devised a five point scale to evaluate outcomes in patients after 5 years of the surgery.[7] Sitzman et al devised a more holistic outcome evaluation system which included clinical and psychosocial domains.[8] The Asher-McDade index evaluated four late post operative outcomes including vermillion border, nasal deviation,

nasal form and nasolabial profile.[9] Numerous such methods of evaluation have been devised however UCL SOE scale was found to be reproducible analytically in laymen and was specific for intra operative immediate post procedure evaluation with photographs.[10]

A method of evaluating cleft lip repairs through videographic analysis has been previously reported.[35] This approach includes not only the assessment of aesthetics, but also the evaluation of lip function and movement. Previous studies have demonstrated that there can be a significant change in lip asymmetry between when the lips are at rest and during speech. However, this evaluation is time consuming and relies on the quality of videography which may lose out on subtle details observable clinically or even in a high resolution photograph.

Wong et al,[36] in 2008, used 3D photogrammetric system to evaluate validity and reliability of facial anthropometric linear distances. Similar systems have been utilised by other researchers such as Meyer-Marcotty et al. (2010), who used a 3D optical sensor system to make three dimensional measurements. The latest developments in 3D photogrammetric techniques have enabled smartphones to capture multiple images of an item and create a 3D mesh by utilizing high-quality graphics processing units. This has made 3D reconstruction possible using our smartphones without the need for expensive sensor systems. Achieving optimal results in this procedure necessitates a stationary subject and adequate illumination, circumstances that may prove challenging to achieve with paediatric patients undergoing clinical examination. However, the process is time-consuming as it requires several hours to construct one meshwork that needs subsequent cleaning and assessment, making the whole procedure laborious.

A study published in 2019 by Patel et al concluded that when separating the complete and incomplete cleft lips, the rotation-advancement technique seemed to have asymmetry in more parameters than the anatomical subunit approach. This seems to

suggest that the outcomes of the anatomical subunit technique are less dependent on cleft lip severity.[37] Four anthropometric parameters were measured using the standardized postoperative photographs: lip height, lip width, vermilion height, and alar base width.

Zaleckas et al concluded, after comparing techniques given by Tennison, Millard and Olekas that height of white lip and symmetry of the Cupid's bow were better restored by using the Tennison technique. The physiological configuration of the white lip and less visible scars were achieved by using the Olekas technique. All techniques were equal in red lip and nose formations.[38]

There have been numerous studies comparing outcomes of different surgeries for unilateral cleft lip repair, however, surgical preference is also based on surgeon’s preference. There are no exclusive studies comparing the Modified Randall-Tennison’s repair and Fisher’s anatomical subunit repair in unilateral cleft lip surgery outcome. There is also lack of aesthetic outcome measurement which may be reproduced by a layman, hence, using the UCL SOE scale for comparison of the two techniques has been proposed for our study.

MATERIAL AND METHODS

This prospective study was conducted on 40 patients with unilateral cleft lip deformity attending the Emergency or OPD at Dayanand Medical College and Hospital Ludhiana from July 2021 to May 2023 willing to be a part of the study. Those, part of the study satisfied the inclusion criteria and none of the exclusion criteria.

7.2 METHOD OF COLLECTION OF DATA

Inclusion Criteria

- Patients with unilateral cleft lip
- Age > 3 months

Exclusion Criteria

- Patients with gross oro-facial deformity.

The patients in the study were divided into two groups of 20 patients each based upon computer generated randomization:

Group A- Patients undergoing Modified Randall-Tennison's repair

Group B- Patients undergoing Fisher's Anatomical Subunit repair

Study Design: This was a prospective randomised study in 40 patients divided into two groups of 20 each. All patients of unilateral cleft lip underwentdetailed assessment in the form of history and clinical examination. After randomization, the procedure for the patient was selected and pre-op photographs taken. Immediately after surgery post procedure intra-operative photographs were taken in two views: frontal and basal.

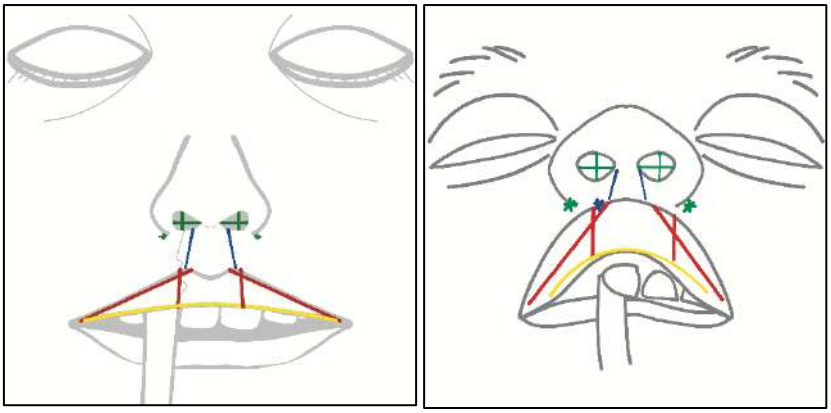


Figure 7: Evaluation via UCL-SOE Scale

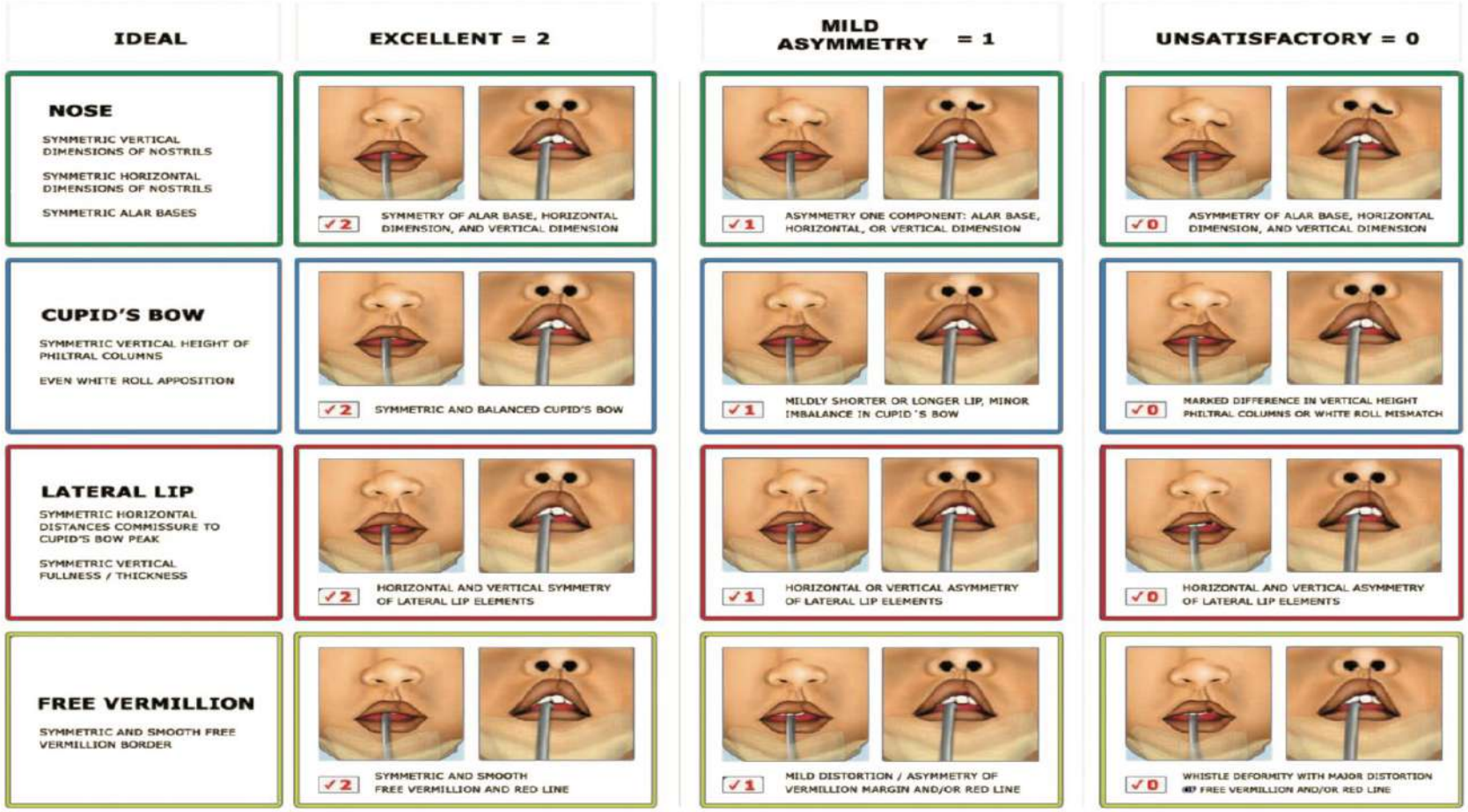
These 2 photographs were handed over to 2 evaluators:

- Surgeon (not from the surgical team)
- Staff nurse

Each of these evaluators provided scores based on Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) scale. The UCL SOE scores symmetry of 4 individual anthropomorphic components of the cleft repair, which can be described as follows:

1) Nose
   a) Symmetry of nostrils in vertical dimensions
   b) Symmetry of nostrils in horizontal dimensions
   c) Symmetry of alar bases
2) Cupid's bow
   a) Symmetry of philtral columns (vertical height)
   b) Precise apposition of white roll
3) Lateral Lip
   a) Symmetry of horizontal distances: commissure-cupid bow peak
   b) Symmetry of vertical fullness/thicknes
4) Free Vermillion
   a) Symmetric and smooth free vermillion border

Figure 8: Scoring via UCL-SOE scale


IDEAL
EXCELLENT = 2
MILD ASYMMETRY = 1
UNSATISFACTORY = 0
NOSE
SYMMETRIC VERTICAL DIMENSIONS OF NOSTRILS
SYMMETRIC HORIZONTAL DIMENSIONS OF NOSTRILS
SYMMETRIC ALAR BASES
✓2 SYMMETRY OF ALAR BASE, HORIZONTAL DIMENSION, AND VERTICAL DIMENSION
✓1 ASYMMETRY ONE COMPONENT: ALAR BASE, HORIZONTAL, OR VERTICAL DIMENSION
✓0 ASYMMETRY OF ALAR BASE, HORIZONTAL DIMENSION, AND VERTICAL DIMENSION
CUPID'S BOW
SYMMETRIC VERTICAL HEIGHT OF PHILTRAL COLUMNS
EVEN WHITE ROLL APPOSITION
✓2 SYMMETRIC AND BALANCED CUPID'S BOW
✓1 MILDLY SHORTER OR LONGER LIP, MINOR IMBALANCE IN CUPID 'S BOW
✓0 MARKED DIFFERENCE IN VERTICAL HEIGHT PHILTRAL COLUMNS OR WHITE ROLL MISMATCH
LATERAL LIP
SYMMETRIC HORIZONTAL DISTANCES COMMISSURE TO CUPID'S BOW PEAK
SYMMETRIC VERTICAL FULLNESS / THICKNESS
✓2 HORIZONTAL AND VERTICAL SYMMETRY OF LATERAL LIP ELEMENTS
✓1 HORIZONTAL OR VERTICAL ASYMMETRY OF LATERAL LIP ELEMENTS
✓0 HORIZONTAL AND VERTICAL ASYMMETRY OF LATERAL LIP ELEMENTS
FREE VERMILLION
SYMMETRIC AND SMOOTH FREE VERMILLION BORDER
✓2 SYMMETRIC AND SMOOTH FREE VERMILLION AND RED LINE
✓1 MILD DISTORTION / ASYMMETRY OF VERMILLION MARGIN AND/OR RED LINE
✓0 WHISTLE DEFORMITY WITH MAJOR DISTORTION OF FREE VERMILLION AND/OR RED LINE

Each element is scored on a 3-point scale: 2 (excellent), 1 (mild asymmetry), 0 (unsatisfactory). The scores of the 4 individual components are then summed for a total score of 0 (lowest) to 8 (highest)

Average score of each patient was calculated.

Scores of the two procedures were compared and evaluated to compare the aesthetic outcome after each procedure.

OUTCOME: To compare the aesthetic outcome of unilateral cleft lip repair between Modified Randall-Tennison's Repair And Fisher's anatomical subunit repair on the basis of Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale

Randomization chart

S.No	Group	S.No	Group
1	A	21	B
2	B	22	A
3	A	23	A
4	B	24	B
5	B	25	B
6	A	26	A
7	B	27	B
8	A	28	A
9	A	29	B
10	B	30	A
11	B	31	B
12	B	32	A
13	B	33	A
14	B	34	A
15	A	35	A
16	B	36	A
17	B	37	A
18	B	38	A
19	A	39	A
20	B	40	B

Statistical Analysis

Data were described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data were normally distributed, a Kolmogorov-Smirnov test was used. Comparison of quantitative variables between the study groups was done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test was performed and exact test was used when the expected frequency is less than 5. A probability value (p value)less than 0.05 was considered statistically significant.All statistical calculations were done using (Statistical Package for the Social Science)SPSS 21version (SPSS Inc., Chicago, IL, USA)statistical program for Microsoft Windows.

OBSERVATION AND RESULTS

The study was conducted prospectively from August 2021 till May 2023 and a total of 40 patients were enrolled in the study in accordance with the inclusion and exclusion criteria. Using a computer-generated randomization these 40 patients were distributed into two groups:

- Group A: 20 patients undergoing Modified Randall-Tennison repair
- Group B: 20 patient's undergoing Fisher's Anatomical Subunit repair

These patients underwent immediate post procedure photographs, and were evaluated for the aesthetic outcome based on the Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) scale.

Demographic analysis

Age

The patients included in the study belonged to the age group of 3 to 10 months. The mean age was 5.97 months. Majority (45%) of the patients belonged to the younger age group of 3-5 months, and only 3 patients that presented late at the age of more than equal to 8 months.

Table 1: Age distribution

Age group (in months)	Frequency	Percentage(%)
0-5	18	45
5-7	14	35
>8	8	20

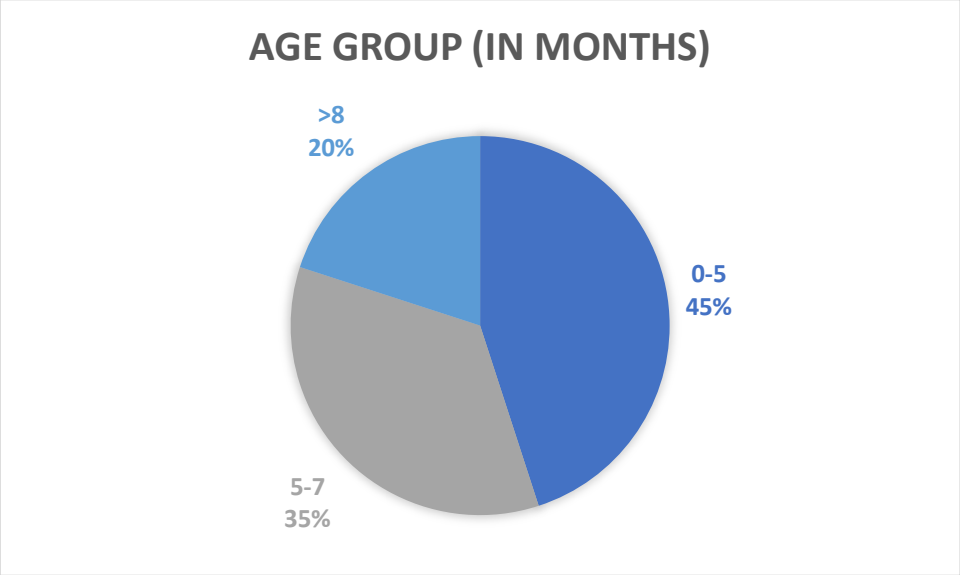


Figure 9: Age distribution (In Months)

Table (2a) Age distribution in Group A

Age group(in months)	Frequency	Percentage
0-4	5	25
5-7	10	50
>8	5	25

Table (2b) Age distribution in Group B

Age group(in months)	Frequency	Percentage
0-4	5	25
5-7	12	60
>8	3	15

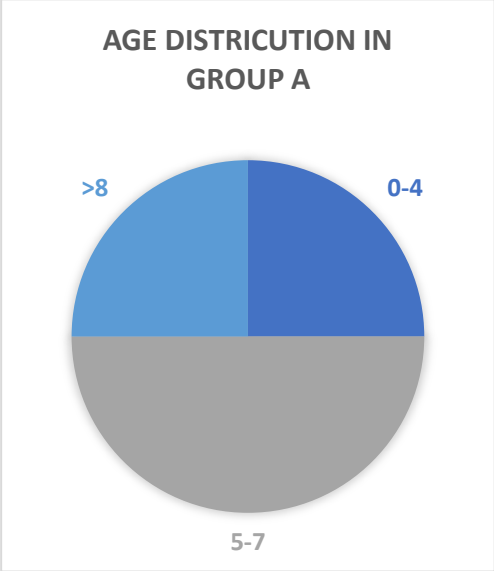


Figure 10 (a) Age Distribution Group A

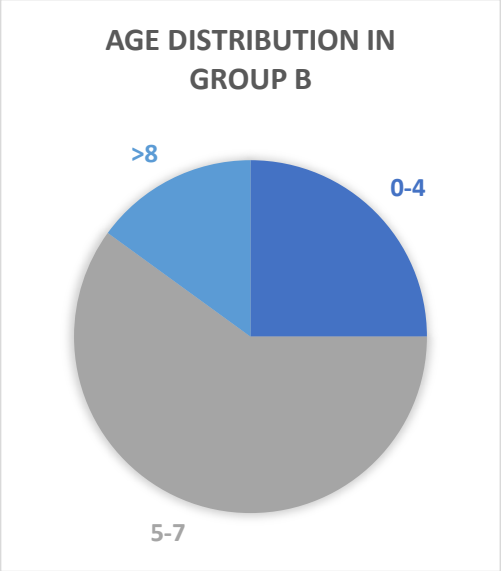


Figure 10 (b) Age Distribution in Group B

The difference between the age distribution of the two groups was not significant with a p-value of 0.3533.

Table 3: Gender distribution

There were 23 (57.5%) males included in the study and 17(42.5% females)

Sex	Frequency	Percentage
Male	23	57.5
Female	17	42.5

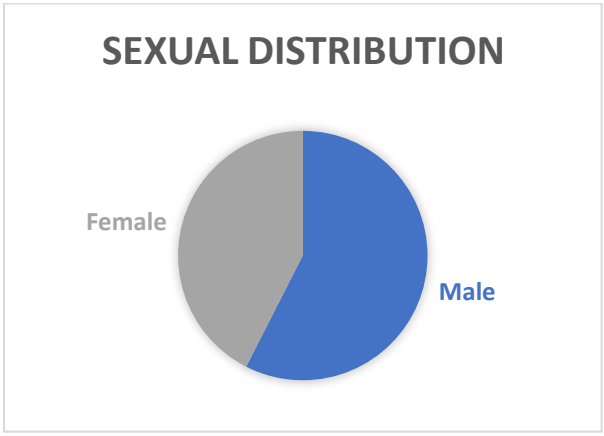


Figure 11: Gender Distribution

Table 4 (a) Gender distribution in Group A

Sex	Frequency	Percentage
Male	10	50
Female	10	50

Table 4 (B) Sex distribution in Group B

Sex	Frequency	Percentage
Male	13	65
Female	7	35

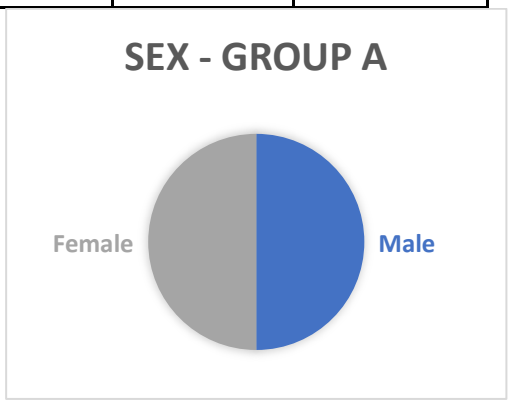


Figure 12 (a): Sex Distribution (Group A)

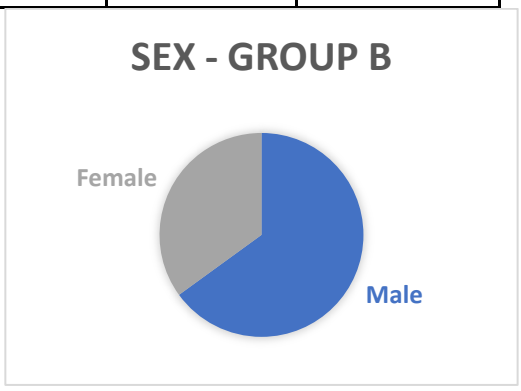


Figure 12 (b): Sex Distribution (Group B)

The difference between the sexual distribution of the two groups was not significant with a p-value of 0.3373.

UCLSOE score by the evaluator (Surgeon)

The two groups were evaluated by a surgeon (not from the surgical team) for the four parameters and their mean was calculated.

The mean for nasal symmetry was 1.2/2.0 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 0.70/2.0. This difference was found to be significant with a p-value of 0.015.

The mean for Cupid's bow symmetry was 1.15 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.10/2.0. This difference wasn't statistically significant.

The mean for lateral lip symmetry was 1.80 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.60/2.0. This difference wasn't statistically significant.

The mean for free vermillion symmetry was 1.60 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.85/2.0. This difference wasn't statistically significant.

The total score for Fisher's Anatomical Subunit repair was 5.75 and that for Modified Randall-Tennison repair was 5.25, however, no statistical significance could be correlated.

Table 5: Comparison of mean scores for UCL-SOE scale between the two groups using evaluation by a surgeon

	FAS		MRT		Z	p-value
	Mean	SD	Mean	SD		
Surgeon Nose	1.20	0.70	0.70	0.47	-2.439	0.015
Surgeon Cupid's Bow	1.15	0.37	1.10	0.55	-0.260	0.795
Surgeon Lateral Lip	1.80	0.41	1.60	0.50	-1.363	0.173
Surgeon Free Vermillion	1.60	0.50	1.85	0.37	-1.748	0.080
Surgeon Total	5.75	0.79	5.25	1.37	-0.985	0.324

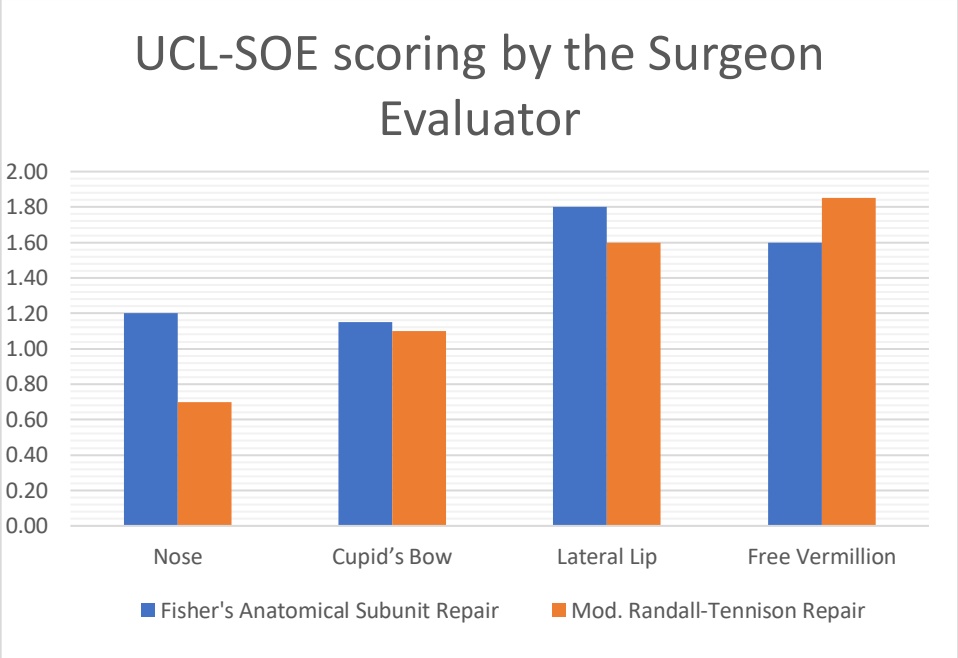


Figure 13: UCL-SOE scoring by the Surgeon Evaluator

UCLSOE score by the evaluator (Nurse)

The two groups were evaluated by a nurse for the four parameters and their mean was calculated.

The mean for nasal symmetry was 1.5/2.0 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 0.65/2.0. This difference was found to be significant with a p-value of 0.001.

The mean for Cupid's bow symmetry was 1.50/2.0 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.35/2.0. This difference wasn't statistically significant.

The mean for lateral lip symmetry was 1.10 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.35/2.0. This difference wasn't statistically significant.

The mean for free vermillion symmetry was 1.45 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.35/2.0. This difference wasn't statistically significant.

The total score for Fisher's Anatomical Subunit repair was 5.55 and that for Modified Randall-Tennison repair was 4.55, however, no statistical significance could be correlated. However, the p-value was 0.059.

Table 6: Comparison of mean scores for UCL-SOE scale between the two groups using evaluation by a nurse

	FAS		MRT		Z	p-value
	Mean	SD	Mean	SD		
Nurse Nose	1.50	0.51	0.65	0.49	-4.110	0.001
Nurse Cupid's Bow	1.50	0.51	1.35	0.59	-0.773	0.439
Nurse Lateral Lip	1.10	0.31	1.20	0.62	-0.788	0.431
Nurse Free Vermillion	1.45	0.51	1.35	0.75	-0.196	0.844
Nurse Total	5.55	0.83	4.55	1.73	-1.891	0.059

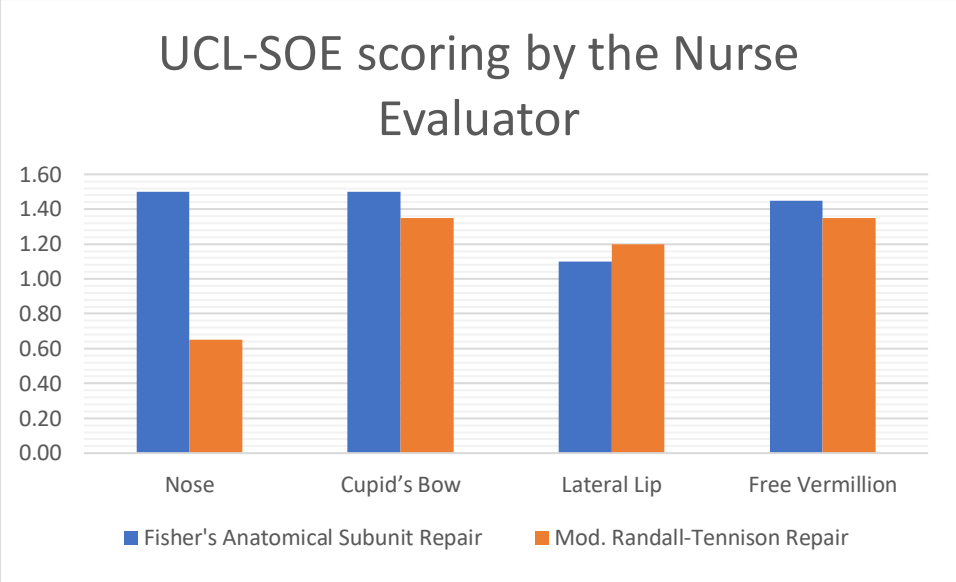


Figure 14: UCL-SOE scoring by the Nurse Evaluator

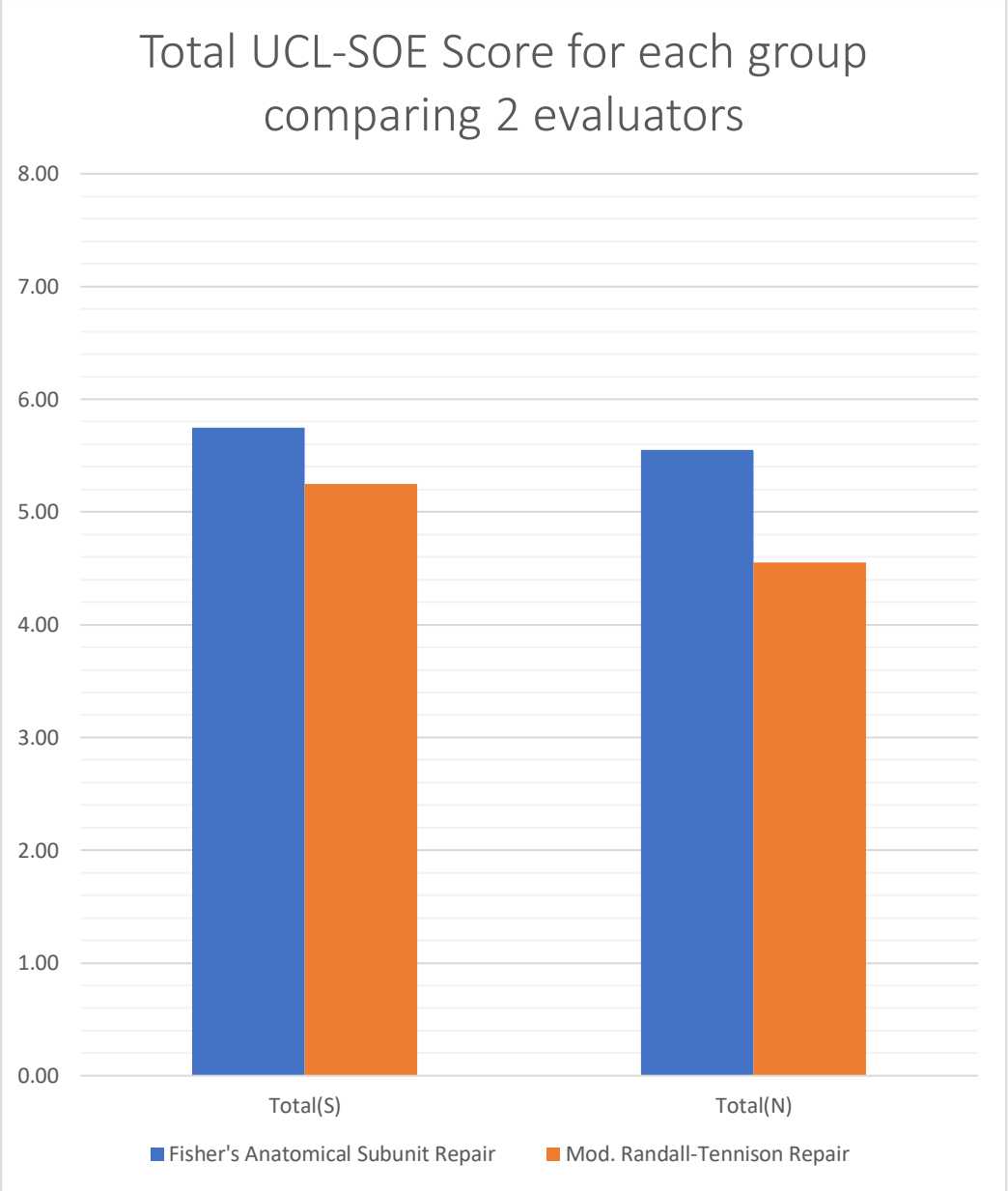


Figure 15: Total UCL-SOE Score for each group comparing 2 evaluators

Average UCLSOE Score

Average score from both the evaluators was calculated for each parameter and then a total score calculated and compared between the two groups.

The mean for nasal symmetry was 1.35/2.0 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 0.68/2.0. This difference was found to be significant with a p-value of 0.001.

The mean for Cupid's bow symmetry was 1.33/2.0 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.23/2.0. This difference wasn't statistically significant.

The mean for lateral lip symmetry was 1.45/2.0 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.40/2.0. This difference wasn't statistically significant.

The mean for free vermillion symmetry was 1.53 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 1.60/2.0. This difference wasn't statistically significant.

The total score for Fisher's Anatomical Subunit repair was 5.65 and that for Modified Randall-Tennison repair was 4.90, and this was found to be significant, statistically, with a p-value of 0.046.

Table 7: Comparison of mean scores for UCL-SOE scale between the two groups using average score of the two evaluators

	FAS		MRT		Z	p-value
	Mean	SD	Mean	SD		
Average Nose	1.35	0.56	0.68	0.34	-3.642	0.001
Average Cupid's Bow	1.33	0.37	1.23	0.34	-0.701	0.483
Average Lateral Lip	1.45	0.28	1.40	0.45	-0.416	0.678
Average Free Vermillion	1.53	0.38	1.60	0.42	-0.772	0.440
Average Total	5.65	0.75	4.90	1.18	-1.997	0.046

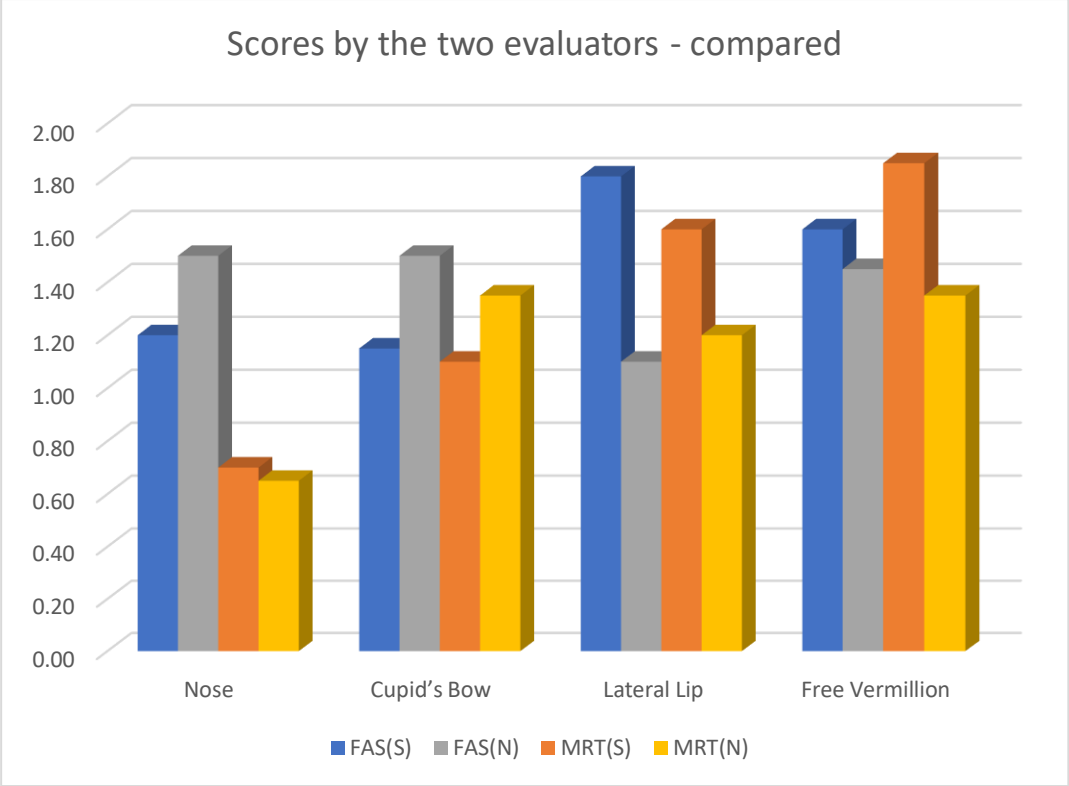


Figure 16: Scores by the two evaluators - compared

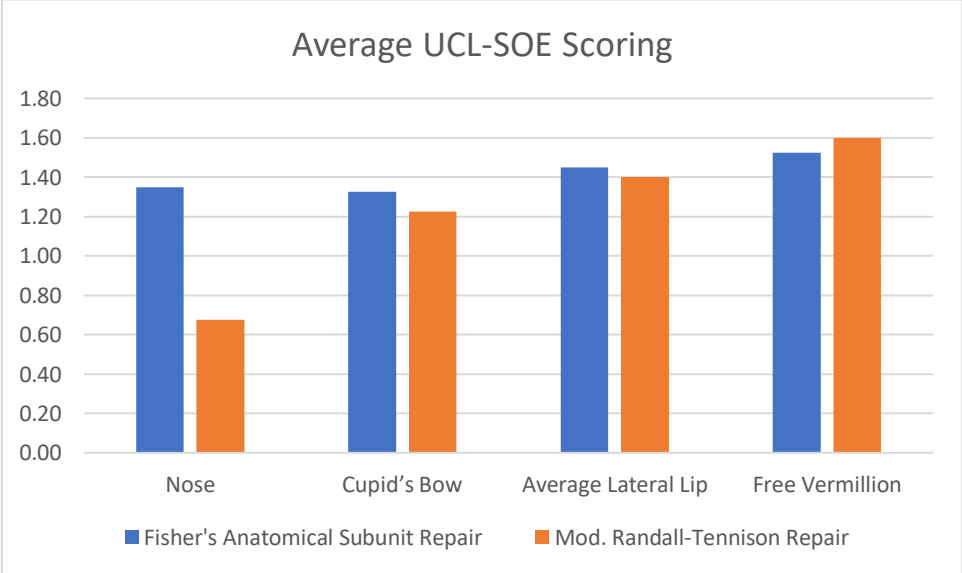


Figure 17: Average UCL-SOE Scoring

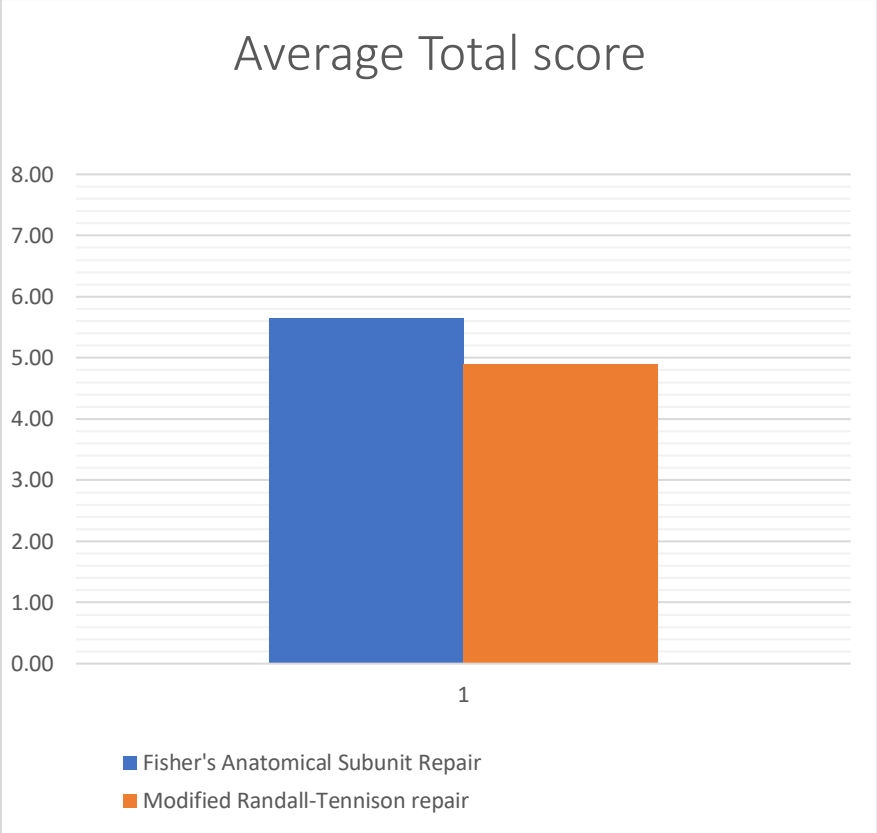


Figure 18: Average Total Score

DISCUSSION

Even though there are multiple surgical techniques for repairing unilateral cleft lip, none of them guarantee perfect outcomes and each technique has its own drawbacks. In an attempt to compare the effectiveness of different methods (references 9-19), several studies have been conducted. However, the absence of standardized criteria poses a challenge in achieving definitive conclusions from such studies.

In 1959, Randall modified the technique of cleft lip repair introduced by Tennison in 1950 for the creation of a triangular flap in the lateral lip element, which was used to add tissue to the upper lip height. Randall-Tennison repair focused on the maintenance of the upper lip height as the prime objective of the surgery.

This involved meticulous measurement of the lip height compared to the non-cleft side and then calculating the need for tissue on the cleft side. This additional height was gained by introducing a triangle from the lateral lip element, with a base length of the required additional height into a wedge (back-cut) on the cleft side till the midline. This technique has widely been accepted as the first surgical repair studied by budding Plastic surgeons, because of its mathematical approach and easy reproducibility.

In 2005, Fisher, published a new technique dwelling over subunit approximation and nasal symmetry in an elaborate and yet another precise, methodological and reproducible technique.

Our objective was to differentiate between these two procedures by utilizing a visual scale that is accessible for individuals who are not experts in the field, allowing them to determine the aesthetic results of each technique.

Age

The patients included in the study belonged to the age group of 3 to 10 months. The mean age at the time of surgery was 5.97 months. Majority (45%) of the patients belonged to the younger age group of 3-5 months. This

is consistent with the recommendation to operate for cleft lip repair at an early age of 3-6 months.[39]

A comparative study between Millard's repair and Randall-Tennison repair form Egypt published in 2021 noted that the average age in months in the two groups was 13.4 months and 19.75 months, respectively.[40]

Gender

Cleft lip and palate is more frequently observedin males than females.[41] Isolated cleft lip also shows almost double the prevalence in males.[42–44] In our investigation, the proportion of males was 57.5%. Despite exhibiting a greater incidence in males, the ratio did not align with conventional research findings which may be attributed to limited sample size. Similar sexual distribution was also seen in other small volume studies,[45] with males slightly more than females.

Outcome assessment for cleft lip surgery

Throughout history, diverse approaches have been employed to assess the aesthetic result of something. Nevertheless, a commonly acknowledged criteria for ascertaining aesthetic result among celft lip patients is absent. It is imperative that any fresh approach meets the requirements of both patients and their guardians by being non-intrusive, excluding exposure to ionizing radiation, expeditious in execution and budget friendly.

UCL SOE score

The average total score for Fisher's Anatomical Subunit repair was 5.65 out of a maximum score of 8, compared to 4.90 for Modified Randall-Tennison repair. This difference was found to be significant with a p-value of 0.046.

Hence, Fisher's Anatomical Subunit repair was found to be aesthetically better than Modified Randall-Tennison repair.

In a study published by Deshmukh et al.[46] in 2018, comparing Mohler's repair with Fisher's Anatomical Subunit repair, using the same scale for outcomes evaluation, Fisher's group got an average score of 5.05 and 4.30 for the Mohler's group, however they noted that more severe cleft lip deformities underwent the Mohler's repair and may

have altered the interpretation of their results. They did not however emphasize on individual components of the scale.

In our scoring system, the four parameters evaluated were :

1. Nasal Symmetry
2. Cupid's Bow
3. Lateral Lip symmetry
4. Free Vermillion

Nasal Symmetry

The average score for Nasal symmetry was 1.35 out of a maximum score of 2 for Fisher's Anatomical Subunit repair and that for Modified Randall-Tennison repair was 0.68. This difference was also found to be statistically significant with a p-value of 0.001 thus contributing the most towards the difference in total scores for aesthetic appearance of the two repairs.

This difference in nasal aesthetics can be attributed to special steps taken during Fisher's Anatomical Subunit repair to ensure nasal symmetry, which is found to be lacking in Modified Randall-Tennison repair. Although the original Randall-Tennison repair does not highlight procedures for ensuring nasal symmetry, most surgeons employ the release of the lower alar cartilage as well as the medial part of the lower lateral cartilage via the original incision. However, this approach is restrictive and does not allow for complete release of nasal cartilage and residual tethering of nasal skin with the presence of typical cleft nasal deformity with this repair.

Fisher, in his original article published in 2005, emphasizes on the following goals in primary rhinoplasty:

1. Centralization of the columellar base
2. Symmetrical alar base repositioning in the craniocaudal plane
3. Nostril margins of equal circumference
4. Release of attachments of the lower lateral cartilage–accessory cartilage complex from the lateral piriform rim to allow for anterior repositioning of the alar base without accentuation of nostril rim buckle and lateral alar flare

5. Anteromedial advancement of the cleft-side lateral crus and dome
6. Creation of normal overlap of the caudal margin of the upper lateral cartilage by the cranial margin of the lateral crus

This is in concordance to our results and further asserts the positive effects seen with Fisher's Anatomical Subunit repair particularly for nasal symmetry.

Cupid's Bow

The average cupid's bow alignment and symmetry score out of a maximum of 2 was 1.45 in Fisher's Anatomical Subunit repair as compared to a score of 1.23 in Modified Randall-Tennison repair. However, this difference was not found to be significant. Hence, both surgeries allow for comparable cupid's bow symmetry and alignment.

Lateral lip

The scores were again comparable between the two groups for lateral lip dimensions and symmetry, with a score of 1.45 for Fisher's Anatomical Subunit repair and 1.40 for Modified Randall-Tennison repair. Despite differences in placement of incisions along the cleft margin, both surgeries allowed for comparable symmetry in terms of lateral lip length and symmetry.

Free Vermillion

Modified Randall-Tennison repair showed a slightly higher score for free vermillion symmetry and continuity with a value of 1.60 as compared to Fisher's Anatomical subunit repair, which had an average value of 1.53. This is the only parameter which showed slightly higher value for Modified Randall-Tennison repair. A study published in 2022, from Austria, by Lux et al.[47] had similar result for vermillion border alignment suggesting that Randall's cleft lip repair may allowfor more accurate alignment of the vermilion border and more adequate correction of the cleft liplength discrepancy in comparison to Pfeifer's wave-line technique. This study employed the established Asher-McDade Index for evaluation.

Limitations of the study

Albeit conducting a meticulous assessment that eliminated any form of bias through the involvement of multiple evaluators and adoption of an uncomplicated scale, our research study had several constraints.In addition to the surgical technique employed, there are several other factors that can impact aesthetic surgical results, including the surgeon's proficiency and personal preferences, as well as variables such as initial severity of the cleft lip and timing of repair.

The limited sample size served only to establish a foundation for the requirement of subsequent studies on a larger scale that can authenticate our findings and conclusions further. Furthermore, we assumed immediate intra-op post procedure photographs being identical to late post-operative aesthetics with regards to delayed setting-in of edema during the post-op period; nevertheless, this assertion may be challengeable since distinct growth patterns in repaired tissue versus normal tissue could yield diverse results at maturity creating demand for long-term research evaluation.

The confounding factor of severity was not taken into account in our study, and only patients with complete unilateral cleft lip were included. Consequently, the assessment of a surgical method based on severity could not be conducted.

Our study did not evaluate for dynamic aesthetic outcomes and did not include functional outcome as a parameter in the scale.

It should be acknowledged that when a 3D subject is projected in 2D, one dimension is inevitably lost during measurement. Nonetheless, for the purpose of creating a scale understandable to non-experts and taking into consideration the significant expenses and specialized personnel required for advanced computer graphics analyses, this constraint was disregarded.

SUMMARY AND CONCLUSION

We conclude that Fisher's anatomical subunit repair is superior to Modified Randall Tennison repair in terms of immediate post procedure aesthetic outcomes. This can be attributed to a superior aesthetic of the nasal symmetry achieved in the Fisher's anatomical subunit repair. Further study is required to establish this claim in a large volume study, perhaps in a late post operative period at the time of maturity.

BIBLIOGRAPHY

1. Farouk A. Critical choices in cleft surgery: 18-year single-surgeon retrospective review of 900 cases. Eur J PlastSurg 2016;39:11–22.

2. Mossey P, Little J. Addressing the challenges of cleft lip and palate research in India. Indian J PlastSurg Off Publ Assoc PlastSurg India 2009;42:S9–18.

3. Iliopoulos C, Mitsimponas K, Lazaridou D, Neukam FW, Stelzle F. A retrospective evaluation of the aesthetics of the nasolabial complex after unilateral cleft lip repair using the Tennison–Randall technique: A study of 44 cases treated in a single cleft center. J Cranio-MaxillofacSurg 2014;42:1679–83.

4. Mulliken JB. Principles and techniques of bilateral complete cleft lip repair. PlastReconstrSurg 1985;75:477–87.

5. Fisher DM. Unilateral cleft lip repair: an anatomical subunit approximation technique. PlastReconstrSurg 2005;116:61–71.

6. Johnson N. An aesthetic index for evaluation of cleft repair. Eur J Orthod 2003;25:243–9.

7. Kim JB, Strike P, Cadier MC. A simple assessment method for auditing multi-centre unilateral cleft lip repairs. J PlastReconstr Aesthetic Surg JPRAS 2011;64:195–200.

8. Sitzman TJ, Allori AC, Thorburn G. Measuring Outcomes in Cleft Lip and Palate Treatment. Clin PlastSurg 2014;41:311–9.

9. Asher-Mcdade C, Roberts C, Shaw WC, Gallager C. Development of a Method for Rating Nasolabial Appearance in Patients with Clefts of the Lip and Palate. Cleft Palate Craniofac J 1991;28:385–91.

10. Campbell A, Restrepo C, Deshpande G, Tredway C, Bernstein SM, Patzer R, et al. Validation of a Unilateral Cleft Lip Surgical Outcomes Evaluation Scale for Surgeons and Laypersons. PlastReconstrSurg Glob Open 2017;5:e1472.

11. Fisher DM, Sommerlad BC. Cleft lip, cleft palate, and velopharyngeal insufficiency. PlastReconstrSurg 2011;128:342e–60e.

12. Boo-Chai K. An ancient Chinese text on a cleft lip. PlastReconstrSurg 1966;38:89–91.

13. Rose W. On Harelip and Cleft Palate. London, H. K. Lewis, 1891. 1891;

14. Thompson J. An artistic and mathematically accurate method of repairing the defects in cases of harelip. SurgGynecolObstet 1912;14:498.

15. Mirault G. Deux lettres sur l'operation du bec-de-lievre. J Chir Paris 1844;2:257.

16. Blair V, Brown, JB. Mirault operation for single harelip. SurgGynecolObstet 1930;51:81.

17. Brown, JB, McDowell, F. Simplified design for repair of single cleft lips. SurgGynecolObstet 1945;80:26.

18. Hagedorn, WH. Hagedorn WH: A modification of the harelip operation. The classic reprint. PlastReconstrSurg 1884;58:89–91.

19. Jalaguier. A propos de la staphylorrhaphie. Bull Mem Soc Chir Paris 1922;

20. LeMESURIER AB. A method of cutting and suturing the lip in the treatment of complete unilateral clefts. PlastReconstrSurg 1946 1949;4:1–12.

21. Tennison CW. The repair of the unilateral cleft lip by the stencil method. PlastReconstrSurg 1946 1952;9:115–20.

22. Randall P. A triangular flap operation for the primary repair of unilateral clefts of the lip. PlastReconstrSurg Transplant Bull 1959;23:331–47.

23. Millard DR. The primary camouflage of the unilateral harelook. 1955. Baltimore, Williams & Wilkins, 1957:160-166.]. Skoog T Ivy R Eds Trans Int Soc PlastSurg First CongrStockh 1955;

24. Demke JC, Tatum SA. Analysis and evolution of rotation principles in unilateral cleft lip repair. J PlastReconstr Aesthetic Surg JPRAS 2011;64:313–8.

25. Olasoji O, Arotiba T, Dogo D. Experience with unoperated cleft lip and palate patients in a Nigerian teaching hospital. Trop Doct 2002;32:33–6.

26. Tan O, Atik B. Triangular with Ala nasi (TAN) repair of unilateral cleft lips: a personal technique and early outcomes. J CraniofacSurg 2007;18:186–97.

27. Millard DR. ROTATION-ADVANCEMENT PRINCIPLE IN CLEFT LIP CLOSURE. Cleft Palate J 1964;12:246–52.

28. Christofides E, Potgieter A, Chait L. A long term subjective and objective assessment of the scar in unilateral cleft lip repairs using the Millard technique without revisional surgery. J PlastReconstr Aesthetic Surg JPRAS 2006;59:380–6.

29. Nollet PJPM, Kuijpers-Jagtman AM, Chatzigianni A, Semb G, Shaw WC, Bronkhorst EM, et al. Nasolabial appearance in unilateral cleft lip, alveolus and palate: a comparison with Eurocleft. J Cranio-Maxillo-facSurg Off PublEur Assoc Cranio-Maxillo-facSurg 2007;35:278–86.

30. Gonzalez-Ulloa M, Castillo A, Stevens E, Alvarez Fuertes G, Leonelli F, Ubaldo F. Preliminary study of the total restoration of the facial skin. PlastReconstrSurg 1946 1954;13:151–61.

31. Burget GC, Menick FJ. The subunit principle in nasal reconstruction. PlastReconstrSurg 1985;76:239–47.

32. Bennett ME, Phillips CL. Assessment of health-related quality of life for patients with severe skeletal disharmony: a review of the issues. Int J Adult OrthodonOrthognathSurg 1999;14:65–75.

33. Farkas LG, Hajnis K, Posnick JC. Anthropometric and anthroposcopic findings of the nasal and facial region in cleft patients before and after primary lip and palate repair. Cleft Palate-Craniofacial J Off Publ Am Cleft Palate-Craniofacial Assoc 1993;30:1–12.

34. Assuncao AG. The V.L.S. classification for secondary deformities in the unilateral cleft lip: clinical application. Br J PlastSurg 1992;45:293–6.

35. Trotman C-A, Faraway JJ, Phillips C. Visual and Statistical Modeling of Facial Movement in Patients with Cleft Lip and Palate. Cleft Palate Craniofac J 2005;42:245–54.

36. Wong JY, Oh AK, Ohta E, Hunt AT, Rogers GF, Mulliken JB, et al. Validity and reliability of craniofacial anthropometric measurement of 3D digital photogrammetric images. Cleft Palate-Craniofacial J Off Publ Am Cleft Palate-Craniofacial Assoc 2008;45:232–9.

37. Patel TA, Patel KG. Comparison of the Fisher Anatomical Subunit and Modified Millard Rotation-Advancement Cleft Lip Repairs: PlastReconstrSurg 2019;144:238e–45e.

38. Zaleckas L, Linkevičienė L, Olekas J, Kutra N. The comparison of different surgical techniques used for repair of complete unilateral cleft lip. Med Kaunas Lith 2011;47:85–90.

39. Schalet G, Langlie J, Kim M, Thaller S. The Rule of 10s for Cleft Repair: A Historical Review of the Literature. J CraniofacSurg 2023;34:884–7.

40. ElMaghraby MF, Ghozlan NA, Ashry MH, Abouarab MH, Farouk A. Comparative study between fisher anatomical subunit approximation technique and millard rotation- advancement technique in unilateral cleft lip repair. Alex J Med 2021;57:92–102.

41. Kumar PS P, S Dhull K, G L, Singh N. Incidence and Demographic Patterns of Orofacial Clefts in Mysuru, Karnataka, India: A Hospital-based Study. Int J Clin Pediatr Dent 2018;11:371–4.

42. Hagberg C, Larson O, Milerad J. Incidence of Cleft Lip and Palate and Risks of Additional Malformations. Cleft Palate Craniofac J 1998;35:40–5.

43. Das SK, Runnels RS, Smith JC, Cohly HHP. Epidemiology of Cleft Lip and Cleft Palate in Mississippi: South Med J 1995;88:437–42.

44. Corona-Rivera JR, Bobadilla-Morales L, Corona-Rivera A, Peña-Padilla C, Olvera-Molina S, Orozco-Martín MA, et al. Prevalence of orofacial

clefts and risks for nonsyndromic cleft lip with or without cleft palate in newborns at a university hospital from West Mexico. CongenitAnom 2018;58:117–23.

45. Adetayo AM, Adetayo MO, Adeyemo WL, James OO, Adeyemi MO. Unilateral cleft lip: evaluation and comparison of treatment outcome with two surgical techniques based on qualitative (subject/guardian and professional) assessment. J Korean Assoc Oral MaxillofacSurg 2019;45:141–51.

46. Deshmukh M, Vaidya S, Deshpande G, Galinde J, Natarajan S. Comparative Evaluation of Esthetic Outcomes in Unilateral Cleft Lip Repair Between the Mohler and Fisher Repair Techniques: A Prospective, Randomized, Observer-Blind Study. J Oral MaxillofacSurg 2019;77:182.e1-182.e8.

47. Lux S, Mayr M, Schwaiger M, Edmondson S-J, Steiner C, Schachner P, et al. Nasolabial Appearance in 5-Year-Old Patients with Repaired Complete Unilateral Cleft Lip and Palate: A Comparison of Two Different Techniques of Lip Repair. J Clin Med 2022;11:2943.

Fisher’s Anatomical Subunit Repair

Picture 1: Pre-op photograph – Frontal

Picture 2: Pre op – Basal

Picture 3: Markings for Fisher’s Anatomical Subunit Repair

Picture 4: Post op – Frontal – Fisher’s Anatomical subunit Repair

Picture 5: Post op – Basal – Fisher’s Anatomical Subunit Repair

Modified Randall-Tennison's Repair

Picture 6: Pre-op Frontal

Picture 7: Pre-op Basal

Picture 8: Post-op Frontal

Picture 9: Post op Basal

					Surgeon				
S. No.	Name	Age in months	Sex	Surgery	Nose	Cupid’s Bow	Lateral Lip	Free Vermillion	Total
1	AK	4	2	MRT	1	2	2	2	7
2	BS	5	1	FAS	2	1	2	2	7
3	PK	3	1	MRT	0	1	1	2	4
4	GK	6	1	FAS	1	1	1	2	5
5	P	7	2	FAS	0	1	2	2	5
6	LS	8	2	MRT	0	1	1	1	3
7	PK	5	2	FAS	1	2	2	2	7
8	R	6	2	MRT	1	1	2	2	6
9	R	8	2	MRT	1	1	2	2	6
10	KK	3	2	FAS	1	1	2	1	5
11	MS	4	1	FAS	2	1	2	1	6
12	NK	5	1	FAS	2	1	2	2	7
13	GJ	4	1	FAS	1	1	1	2	5
14	B	7	2	FAS	0	1	2	2	5
15	N	11	1	MRT	1	1	1	2	5
16	AS	8	1	FAS	1	2	2	2	7
17	R	4	1	FAS	1	1	2	1	5
18	BP	10	1	FAS	2	1	2	1	6
19	AK	6	1	MRT	1	2	2	2	7
20	A	4	1	FAS	2	1	2	1	6
21	M	7	1	FAS	1	1	1	2	5
22	J	4	1	MRT	0	1	2	2	5
23	H	8	2	MRT	1	0	1	1	3
24	AK	5	1	FAS	0	1	2	2	5
25	Y	6	2	FAS	1	2	2	1	6
26	GK	4	1	MRT	1	1	2	2	6
27	SP	6	2	FAS	1	1	2	2	6
28	A	7	1	MRT	1	1	2	2	6
29	T	5	1	FAS	2	1	2	1	6
30	D	7	2	MRT	1	1	1	2	5
31	D	8	2	FAS	2	1	2	1	6
32	J	5	1	MRT	1	2	2	2	7
33	P	6	1	MRT	0	1	1	2	4
34	Y	7	2	MRT	0	0	2	1	3
35	J	5	2	MRT	1	1	2	2	6
36	SP	7	2	MRT	1	1	2	2	6
37	AP	4	1	MRT	1	1	1	2	5
38	AK	9	2	MRT	1	2	2	2	7
39	S	6	1	MRT	0	1	1	2	4
40	JK	5	1	FAS	1	1	1	2	5

	Nurse					Average				
S. No.	Nose	Cupid’s Bow	Lateral Lip	Free Vermillion	Total	Nose	Cupid’s Bow	Lateral Lip	Free Vermillion	Total
1	0	2	1	1	4	0.5	2	1.5	1.5	5.5
2	2	2	1	2	7	2	1.5	1.5	2	7
3	0	1	1	1	3	0	1	1	1.5	3.5
4	2	1	1	1	5	1.5	1	1	1.5	5
5	1	1	1	1	4	0.5	1	1.5	1.5	4.5
6	1	1	1	0	3	0.5	1	1	0.5	3
7	1	2	2	1	6	1	2	2	1.5	6.5
8	1	2	2	2	7	1	1.5	2	2	6.5
9	1	1	2	2	6	1	1	2	2	6
10	1	1	1	2	5	1	1	1.5	1.5	5
11	2	2	1	1	6	2	1.5	1.5	1	6
12	2	2	1	2	7	2	1.5	1.5	2	7
13	2	1	1	1	5	1.5	1	1	1.5	5
14	1	1	1	2	5	0.5	1	1.5	2	5
15	0	2	1	1	4	0.5	1.5	1	1.5	4.5
16	1	2	1	1	5	1	2	1.5	1.5	6
17	1	1	1	2	5	1	1	1.5	1.5	5
18	2	2	1	1	6	2	1.5	1.5	1	6
19	0	1	1	1	3	0.5	1.5	1.5	1.5	5
20	2	2	1	2	7	2	1.5	1.5	1.5	6.5
21	2	1	1	1	5	1.5	1	1	1.5	5
22	1	1	0	1	3	0.5	1	1	1.5	4
23	1	2	1	2	6	1	1	1	1.5	4.5
24	1	1	1	2	5	0.5	1	1.5	2	5
25	1	2	2	1	6	1	2	2	1	6
26	1	2	2	2	7	1	1.5	2	2	6.5
27	1	1	1	2	5	1	1	1.5	2	5.5
28	1	1	1	2	5	1	1	1.5	2	5.5
29	2	2	1	1	6	2	1.5	1.5	1	6
30	0	2	1	2	5	0.5	1.5	1	2	5
31	2	2	1	1	6	2	1.5	1.5	1	6
32	0	1	1	1	3	0.5	1.5	1.5	1.5	5
33	1	1	2	0	4	0.5	1	1.5	1	4
34	1	2	1	2	6	0.5	1	1.5	1.5	4.5
35	1	1	2	2	6	1	1	2	2	6
36	1	1	2	1	5	1	1	2	1.5	5.5
37	1	2	1	2	6	1	1.5	1	2	5.5
38	1	1	1	2	5	1	1.5	1.5	2	6
39	0	0	0	0	0	0	0.5	0.5	1	2
40	1	1	1	2	5	1	1	1	2	5

of Health Sciences
Sadiq Road
Faridkot-151 203 (PB) INDIA
Phone: 01639-256230,256236
Tele/Fax: 01639-256235
Email: Examination@bfuhs.ac.in

No. BFUHS/2K21p-III/ 97

Date 25/10/21

The Principal,
DMC, Ludhiana.

Subject: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 29.10.2021 has approved the plan of thesis of **Sumit Singh Gautam**, a student of your college for **MCh Plastic & Reconstructive Surgery** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Comparative study of modified randall-tennison's repair and fisher's anatomical subunit repair in unilateral cleft lip patients.

Supervisor
Dr. Ramneesh Garg
Prof.,
Dept. of Plastic Surgery,
DMCH, Ludhiana.

Co-Supervisor
Dr. Rajinder Mittal
Prof. & Head,
Dept. of Plastic Surgery,
DMCH, Ludhiana.

The student has to submit the four copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic,(if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note :

181. If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.

182. The student may submit the thesis as per the schedule already conveyed i.e for May/June examination 30th Nov of the preceding the year of examination and for Nov/Dec examinations 31st May of the year of examination.

COMPARATIVE STUDY OF MODIFIED RANDALL-TENNISON'S REPAIR AND FISHER'S ANATOMICAL SUBUNIT REPAIR IN UNILATERAL CLEFT LIP PATIENTS

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

M.Ch.

IN

PLASTIC AND RECONSTRUCTIVE SURGERY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES
FARIDKOT

AUGUST, 2021

DR. SUMIT SINGH GAUTAM

DEPARTMENT OF PLASTIC AND RECONSTRUCTIVE SURGERY
DAYANAND MEDICAL COLLEGE & HOSPITAL,
LUDHIANA

ABSTRACT OF PLAN OF THESIS

Title	COMPARATIVE STUDY OF MODIFIED RANDALL-TENNISON'S REPAIR AND FISHER'S ANATOMICAL SUBUNIT REPAIR IN UNILATERAL CLEFT LIP PATIENTS
For the degree of	M.Ch Plastic and Reconstructive Surgery
Name of the candidate	Dr. Sumit Singh Gautam
Supervisor	Dr. Ramneesh Garg, Professor, Department of Plastic and Reconstructive Surgery , DMCH, Ludhiana
Co-supervisor	Dr. Rajinder Mittal, Professor & Head, Department of Plastic and Reconstructive Surgery, DMCH, Ludhiana
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: For evaluation of this aesthetic outcome different study groups have utilized different parameters, however there is a lack of a standardized scoring system which can be utilized by even a layman. Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale[5] is one such scale which allows analysis of photographs taken in immediate post procedure intra operative period.

Aim of Study: To compare the aesthetic outcome of unilateral cleft lip repair between Modified Randall-Tennison's Repair And Fisher's anatomical subunit repair on the basis of Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale

Materials & Methods: This will be a prospective randomised study in 40 patients divided into two groups of 20 each undergoing Modified Randall-Tennison's Repair and Fisher's anatomical subunit repair and then evaluation of their aesthetic outcome in the immediate post procedure intra operative period based on UCL SOE scale

Clinical Significance: To compare the aesthetic outcome of unilateral cleft lip repair between Modified Randall-Tennison's Repair And Fisher's anatomical subunit repair on the basis of Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale

Keywords: Unilateral Cleft Lip Surgical Outcomes Evaluation, Modified Randall-Tennison's Repair, Fisher's anatomical subunit repair

(Signature)	(Signature)	(Signature)	(Signature)
Candidate	Co-Supervisor	Supervisor	Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"COMPARATIVE STUDY OF MODIFIED RANDALL-TENNISON'S REPAIR AND FISHER'S ANATOMICAL SUBUNIT REPAIR IN UNILATERAL CLEFT LIP PATIENTS"** exist in the Department of Plastic and Reconstructive surgery, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis is genuine and is collected by the candidate himself under our supervision and guidance.

Supervisor

Dr. Ramneesh Garg
Professor
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Co-Supervisor

Dr. Rajinder Mittal
Professor & Head
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Head of the Department

Dr. Rajinder Mittal
Professor & Head
Department of Plastic &
Reconstructive Surgery
DMCH, Ludhiana

Place: Ludhiana

Date : 28-8-21

APPROVAL PROFORMA
BY RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Dr. Sumit Singh Gautam
Department	Plastic and Reconstructive Surgery
Topic of Thesis	Comparative study of Modified Randall-Tennison's Repair and Fisher's Anatomical Subunit Repair in Unilateral Cleft Lip Patients
Likely date of appearing in PG examination	May/June 2023
Date of enrollment	26.12.2020
Name of Head of Department	Dr. Rajinder Mittal
1) Supervisor **2) Co-Supervisor(s)**	Dr. Ramneesh Garg Dr. Rajinder Mittal
Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Harpreet Kaur (Professor & Head, Pathology)	Mr. R K Sharma (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. Ramit Mahajan (Associate Professor, Gastroenterology)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)	Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)
Dr. Gurpreet S Wander (Vice Principal)	Dr. Gurpreet S Wander (Vice Principal & Professor & Head, Cardiology)
	Dr. Gagandeep Singh (Secretary, Ethics Committee Professor & Head, Neurology)

Approved: Yes / No

Dr. Sandeep Puri
Chairperson
Research Committee
Chairperson
Research Committee

Approved: Yes / ~~No~~

Prof. Arvind Malhotra
Chairperson
Ethics Committee
Chairperson
Ethics Committee

BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	Sumit Singh Gautam V.P.O. Thural, Distt. Kangra H.P. 176107
2	NAME OF THE INSTITUTE	Dayanand Medical College & Hospital, Ludhiana
3	COURSE OF STUDY AND SUBJECT	M.Ch. in Plastic and Reconstructive Surgery
4	DATE OF ADMISSION OF COURSE	26/12/20
5	TITLE OF THE TOPIC	Comparative study of Modified Randall-Tennison's Repair and Fisher's Anatomical Subunit Repair in Unilateral Cleft Lip Patients

6.0 BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR STUDY

A cleft lip is one of the most common congenital malformations, with a mean incidence of 1/1000 live births worldwide.[1] In India, out of the 24.5 million births per year, the birth prevalence of clefts is somewhere between 27,000 and 33,000 clefts per year.[2]

The main categories of orofacial deformities are isolated cleft palate and cleft lip with or without cleft palate. These may present as part of a syndrome or other associated abnormalities. Affected children have a range of functional as well as aesthetic problems. These include feeding difficulties at birth due to problems with oral seal, swallowing and nasal regurgitation, hearing difficulties due to abnormalities in the palatal musculature, and speech difficulties due to nasal escape and articulation problems.

It may not be the end of life but for children with cleft, the problem goes beyond the obvious disfigurement of face and extends to repeated infections, social stigma, and mental impairment that affect the speech, hearing, and teeth formation. These children are teased about their cleft-related features such as speech, teeth, and lip appearance and lose self-confidence.[3] Research has shown that attractive children are seen by others as brighter, as having more positive social behavior and receive more positive treatment than their less attractive cleft counterparts. These children suffer with emotional “burn out” in adolescence.

These cleft defects can be surgically repaired in childhood, but residual deformity due to scarring and abnormal facial development results in continuing functional and psychosocial problems. Thus, clefts have a prolonged, adverse influence on the health and social integration of affected individuals.[2]

The unilateral cleft lip deformity presents with a paucity of tissue between the nasal sill superiorly and the lip inferiorly. It involves a full-thickness defect of the lip (and possibly the alveolar ridge and palate),

from the base of the nose to the free margin of the oral cavity. The underlying palatal shelves may be similarly clefted and malpositioned, contributing to the deformity. Repair involves anatomic re-creation of the lip elements on the uninvolved side of the lip.

Numerous techniques have been defined for the aesthetic outcome of a cleft lip repair. The main idea of all these techniques is the precise dissection of the orbicularis oris pathological muscle insertions around the cleft, and their reinsertion into the correct anatomical position, in order to reconstruct the normal nasolabial anatomy.[4] The goals of unilateral cleft lip repair are both functional and aesthetic. Aesthetically the goals of surgical intervention include formation of lip continuity, establishing symmetry of the cupid's bow and the nose in a manner that places scars in less discernible areas.

For evaluation of this aesthetic outcome different study groups have utilized different parameters, however there is a lack of a standardized scoring system which can be utilized by even a layman. Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale[5] is one such scale which allows analysis of photographs taken in immediate post procedure intra operative period. The UCL SOE scores symmetry of 4 individual anthropomorphic components of the cleft repair (Cupid’s bow, lateral lip, nose, and free vermillion).

Techniques differ in the capability to achieve lip lengthening, configuration of the alar base and nasal floor as well as the resulting scar shape and length. Various techniques of lip repair have been described, each of which position the cutaneous scar uniquely.

There are no exclusive studies comparing aesthetic outcomes based on Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale. Therefore, the purpose of this study is to compare the aesthetic outcomes for patients with unilateral cleft lip undergoing Modified Randall-Tennison’s repair or Fisher’s anatomical subunit repair.

6.2 REVIEW OF LITERATURE

The pathologic origins of a cleft lip are traceable to distinct embryological events. The fusion failure during gestational weeks 4–7 of facial primordia: the central frontonasal prominence and two lateral maxillary prominences result in a typical cleft lip of a new born. Surgical management hinges upon the accurate identification of involved structures and methodical attention to detail in surgical techniques in reconstruction.

The unilateral cleft typically results in a disruption of cupid's bow and the absence of one philtral column. The continuity of the orbicularis oris circumferentially is compromised, with abnormal insertions. In the lateral lip element, the upper part of cutaneous orbicularis (Pars Superficialis) inserts in the lateral aspect of the alar base and the nasolabial fold, while the lower part inserts into the nostril base periosteum of the pyriform rim. In the medial lip element, the cutaneous orbicularis (pars superficialis) inserts into the anterior nasal spine and columella. The deep orbicularis (pars marginalis) is simply interrupted by the cleft deficiency and results in a diminished vermillion-cutaneous ridge at the cleft margin.[6]

The goals of unilateral cleft lip repair are both functional and aesthetic. In order to address these goals, one must understand the anatomical characteristics of unilateral cleft lip. Aesthetically the goals of surgical intervention include formation of lip continuity, establishing symmetry of the cupid's bow and the nose in a manner that places scars in less discernable areas. Recreation of the orbicularis muscle to circumferentially surround the opening of the oral cavity is important for long-lasting cosmetic outcomes and lip and mouth function.

The treatment of children with cleft lip deformity has long challenged surgeons. Numerous surgical techniques have been developed to restore function, symmetry, and aesthetics. Early surgical techniques in treatment of cleft lip deformity involved straight-line repairs were limited in restoring symmetry to the lip of a child with unilateral cleft lip.

Straight line techniques have the potential for scar contracture with consequent shortening of the lip, as excess normal tissue along the cleft margins is sacrificed to achieve straightline closure and the shape of Cupid's bow is blunted.[7] These shortcomings have led to the use of geometrically designed flaps. Theoretical advantages of geometric techniques include applicability to a wide range of cleft sizes, the ability to symmetrically recreate Cupid's bow, achievement of adequate rotation and lip length, increased fullness of the philtral tubercle, and minimal wasted tissue.[8,9] LeMesurier and Tennison[10] developed the use of flaps that allowed reconstruction of the cupid's bow of the lip. Millard's technique[11] of "rotation-advancement" brought about the modern era of cleft lip reconstruction. Later refinements by Salyer, Noordhoff, Cutting, and others have allowed the surgeon to more effectively restore function, symmetry, and aesthetics. Fisher described a hybrid technique in 2005 that is termed the anatomical subunit approximation technique.[12]

The ideal operation for repair of a unilateral cleft lip should result in a symmetrical upper lip with equal philtral column length on either side. The scar should mirror the opposite side and should not transgress the philtral column. There should also be no peaking at Cupid's bow at the cleft side or notching of the vermillion. In addition, Cupid's bow should be of adequate proportions.[13] Christofides and others opined that these criteria should be obtainable in a single operation without multiple minor revisional procedures.[14]

Assessment of the appearance of the cleft-related deformity and the impact of surgical treatment is a critical component of the quality of life outcome for this patient pool.[15] Nasolabial appearance is, arguably, one of the most important measures of the success of treatment for unilateral cleft lip.[16] Researchers have created and tested scales, but proposed methods vary widely in their study design, patient population, treatment stage, type of cleft, evaluators' education, and familiarity with the patients and techniques.

Methods to assess nasolabial appearance can be broadly divided into qualitative and quantitative methods. The latter methods aim to analyze the extent of abnormal morphology and the degree of disproportion objectively through facial measurements.[17] Qualitative methods are more subjective and involve analyses of facial esthetic and appearance impairment using scales, indices, scoring systems, and rankings. Subjective assessment of appearance and aesthetics is fraught with difficulty, but is most likely to reflect the patient's and general public's perception of facial impairment.[18]

Johnson N et al devised an aesthetic index for evaluation of cleft repair which was proven reproducible.[18] This index evaluated late post op outcomes. Kim et al devised a five point scale to evaluate outcomes in patients after 5 years of the surgery.[19] Sitzman et al devised a more holistic outcome evaluation system which included clinical and psychosocial domains.[20] The Asher-McDade index evaluated four late post operative outcomes including vermillion border, nasal deviation, nasal form and nasolabial profile.[16] Numerous such methods of evaluation have been devised however UCL SOE scale was found to be reproducible analytically in laymen and was specific for intra operative immediate post procedure evaluation with photographs.[5]

A study published in 2019 by Patel et al concluded that when separating the complete and incomplete cleft lips, the rotation-advancement technique seemed to have asymmetry in more parameters than the anatomical subunit approach. This seems to suggest that the outcomes of the anatomical subunit technique are less dependent on cleft lip severity.[21] Four anthropometric parameters were measured using the standardized postoperative photographs: lip height, lip width, vermilion height, and alar base width.

Zaleckas et al concluded, after comparing techniques given by Tennison, Millard and Olekas that height of white lip and symmetry of the Cupid's bow were better restored by using the Tennison technique. The physiological configuration of the white lip and less visible scars

were achieved by using the Olekas technique. All techniques were equal in red lip and nose formations.[22]

There have been numerous studies comparing outcomes of different surgeries for unilateral cleft lip repair, however, surgical preference is also based on surgeon's preference. There are no exclusive studies comparing the Modified Randall-Tennison's repair and Fisher's anatomical subunit repair in unilateral cleft lip surgery outcome. There is also lack of aesthetic outcome measurement which may be reproduced by a layman, hence, using the UCL SOE scale for comparison of the two techniques has been proposed for our study.

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare the aesthetic outcome of unilateral cleft lip repair between Modified Randall-Tennison's Repair And Fisher's anatomical subunit repair on the basis of Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale

7.0 MATERIAL AND METHODS

7.1 SOURCE OF DATA

This prospective study will be conducted on 40 patients with unilateral cleft lip deformity attending the Emergency or OPD at Dayanand Medical College and Hospital Ludhiana, willing to be a part of the study. Those part of the study shall have to satisfy the inclusion criteria and none of the exclusion criteria.

7.2 METHOD OF COLLECTION OF DATA

Inclusion Criteria

- Patients with unilateral cleft lip
- Age > 3 months

Exclusion Criteria

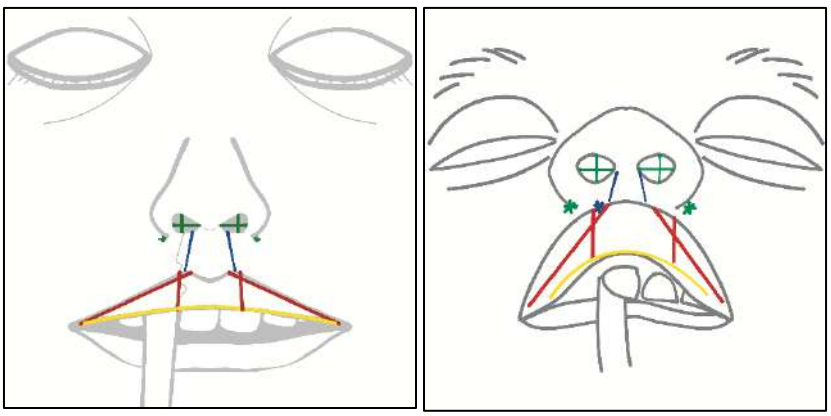
- Patients with gross oro-facial deformity.

The patients in the study will be divided into two groups of 20 patients each based upon computer generated randomization:

Group A- Patients undergoing Modified Randall-Tennison's repair

Group B- Patients undergoing Fisher's Anatomical Subunit repair

Study Design: This will be a prospective randomised study in 40 patients divided into two groups of 20 each. All patients of unilateral cleft lip will undergo detailed assessment in the form of history and clinical examination. After randomization, the procedure for the patient will be selected and pre-op photographs taken. Immediately after surgery post procedure intra-operative photographs will be taken in two views: frontal and basal.

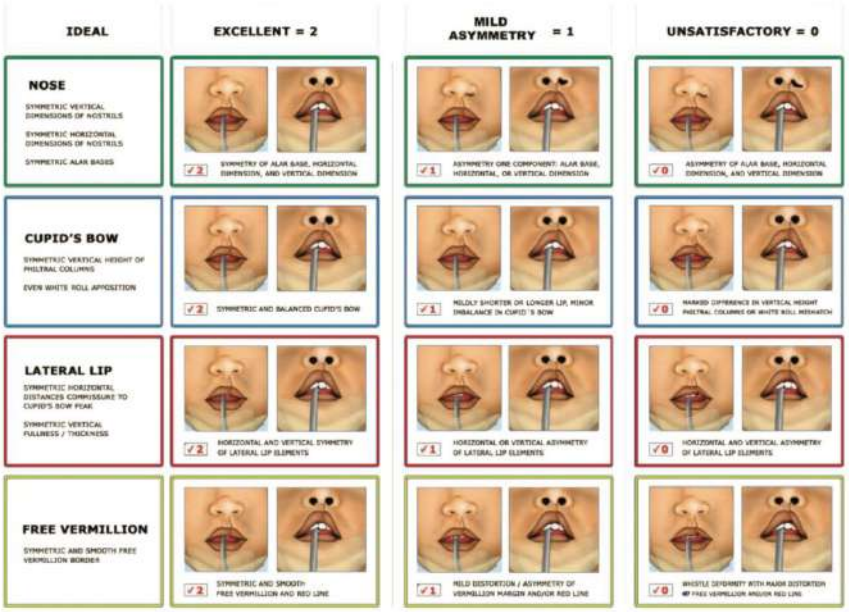


These 2 photographs will be handed over to 2 evaluators:

- Surgeon (not from the surgical team)
- Staff nurse

Each of these evaluators will provide scores based on Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) scale. The UCL SOE scores symmetry of 4 individual anthropomorphic components of the cleft repair, which can be described as follows:

1) Nose
    a) Symmetry of nostrils in vertical dimensions
    b) Symmetry of nostrils in horizontal dimensions
    c) Symmetry of alar bases
2) Cupid's bow
    a) Symmetry of philtral columns (vertical height)
    b) Precise apposition of white roll
3) Lateral Lip
    a) Symmetry of horizontal distances: commissure-cupid bow peak
    b) Symmetry of vertical fullness/thickness
4) Free Vermillion
    a) Symmetric and smooth free vermillion border



Each element is scored on a 3-point scale: 2 (excellent), 1 (mild asymmetry), 0 (unsatisfactory). The scores of the 4 individual

components are then summed for a total score of 0 (lowest) to 8 (highest)

Average score of each patient will be calculated.

Scores of the two procedures will be compared and evaluated to compare the aesthetic outcome after each procedure.

OUTCOME: To compare the aesthetic outcome of unilateral cleft lip repair between Modified Randall-Tennison's Repair And Fisher's anatomical subunit repair on the basis of Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale

STATISTICAL ANALYSIS: Data were described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data were normally distributed, a Kolmogorov-Smirnov test was used. Comparison of quantitative variables between the study groups was done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test was performed and exact test was used when the expected frequency is less than 5. A probability value (p value)less than 0.05 was considered statistically significant. All statistical calculations were done using (Statistical Package for the Social Science)SPSS 21version (SPSS Inc., Chicago, IL, USA)statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached herewith

8.0 LIST OF REFERENCES

1. Farouk A. Critical choices in cleft surgery: 18-year single-surgeon retrospective review of 900 cases. Eur J Plast Surg. 2016;39:11–22.
2. Mossey P, Little J. Addressing the challenges of cleft lip and palate research in India. Indian J Plast Surg. 2009;42:S9–18.
3. Hunt O, Burden D, Hepper P, Johnston C. The psychosocial effects of cleft lip and palate: a systematic review. European Journal of Orthodontics. 2005;27:274–85.
4. Iliopoulos C, Mitsimponas K, Lazaridou D, Neukam FW, Stelzle F. A retrospective evaluation of the aesthetics of the nasolabial complex after unilateral cleft lip repair using the Tennison–Randall technique: A study of 44 cases treated in a single cleft center. Journal of Cranio-Maxillofacial Surgery. 2014;42:1679–83.
5. Campbell A, Restrepo C, Deshpande G, Tredway C, Bernstein SM, Patzer R, et al. Validation of a Unilateral Cleft Lip Surgical Outcomes Evaluation Scale for Surgeons and Laypersons. Plast Reconstr Surg Glob Open. 2017;5:e1472.
6. Bo C, Ningbei Y. Reconstruction of upper lip muscle system by anatomy, magnetic resonance imaging, and serial histological sections. J Craniofac Surg. 2014;25:48–54.
7. Demke JC, Tatum SA. Analysis and evolution of rotation principles in unilateral cleft lip repair. J Plast Reconstr Aesthet Surg. 2011;64:313–8.
8. Olasoji O, Arotiba T, Dogo D. Experience with unoperated cleft lip and palate patients in a Nigerian teaching hospital. Trop Doct. 2002;32:33–6.
9. Tan O, Atik B. Triangular with Ala nasi (TAN) repair of unilateral cleft lips: a personal technique and early outcomes. J Craniofac Surg. 2007;18:186–97.
10. Randall P. A triangular flap operation for the primary repair of unilateral clefts of the lip. Plast Reconstr Surg Transplant Bull. 1959;23:331–47.

11. Millard DR. Rotation-Advancement Principle in Cleft Lip Closure. Cleft Palate J. 1964;12:246–52.
12. Fisher DM. Unilateral Cleft Lip Repair: An Anatomical Subunit Approximation Technique: Plastic and Reconstructive Surgery 2005;116:61–71.
13. Christofides E, Potgieter A, Chait L. A long term subjective and objective assessment of the scar in unilateral cleft lip repairs using the Millard technique without revisional surgery. J Plast Reconstr Aesthet Surg. 2006;59:380–6.
14. Nollet PJPM, Kuijpers-Jagtman AM, Chatzigianni A, Semb G, Shaw WC, Bronkhorst EM, et al. Nasolabial appearance in unilateral cleft lip, alveolus and palate: a comparison with Eurocleft. J Craniomaxillofac Surg. 2007;35:278–86.
15. Bennett ME, Phillips CL. Assessment of health-related quality of life for patients with severe skeletal disharmony: a review of the issues. Int J Adult Orthodon Orthognath Surg. 1999;14:65–75.
16. Asher-Mcdade C, Roberts C, Shaw WC, Gallager C. Development of a Method for Rating Nasolabial Appearance in Patients with Clefts of the Lip and Palate. The Cleft Palate-Craniofacial Journal 1991;28:385–91.
17. Farkas LG, Hajnis K, Posnick JC. Anthropometric and anthroposcopic findings of the nasal and facial region in cleft patients before and after primary lip and palate repair. Cleft Palate Craniofac J. 1993;30:1–12.
18. Johnson N. An aesthetic index for evaluation of cleft repair. The European Journal of Orthodontics. 2003;25:243–9.
19. Kim JB, Strike P, Cadier MC. A simple assessment method for auditing multi-centre unilateral cleft lip repairs. J Plast Reconstr Aesthet Surg. 2011;64:195–200.
20. Sitzman TJ, Allori AC, Thorburn G. Measuring Outcomes in Cleft Lip and Palate Treatment. Clinics in Plastic Surgery. 2014;41:311–9.

21. Patel TA, Patel KG. Comparison of the Fisher Anatomical Subunit and Modified Millard Rotation-Advancement Cleft Lip Repairs: Plastic and Reconstructive Surgery. 2019;144:238e–45e.
22. Zaleckas L, Linkevičienė L, Olekas J, Kutra N. The comparison of different surgical techniques used for repair of complete unilateral cleft lip. Medicina (Kaunas). 2011;47:85–90.

Study Proforma

Patient Particulars:

Serial Number:

Name	
Age / Sex	
MRD. No.	
Address	
Date of Surgery	

Surgery performed: Modified Randall Tennison Repair / Fisher's Anatomical Subunit repair

Pre-op Photograph

Signature of Candidate

Signature of Supervisor

Evaluator Card:

Post procedure photograph : Frontal

Post procedure photograph : Basal

Unilateral Cleft Lip Surgical Outcomes Evaluation (UCL SOE) Scale

Evaluator 1:

	Score
Nose	/2
Cupid's Bow	/2
Lateral Lip	/2
Free Vermillion	/2
Total Score	/8

Evaluator 2:

	Score
Nose	/2
Cupid's Bow	/2
Lateral Lip	/2
Free Vermillion	/2
Total Score	/8

Average Score:

Signature of Candidate

Signature of Supervisor

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o..... ..... am willing to participate in the study **"Comparative study of Modified Randall-Tennison's Repair and Fisher's Anatomical Subunit Repair in Unilateral Cleft Lip Patients"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

.....
Signature of the Witness

Name:

.....
Signature of the patient

Signature of Candidate

Signature of Supervisor

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य **"Comparative study of Modified Randall-Tennison's Repair and Fisher's Anatomical Subunit Repair in Unilateral Cleft Lip Patients"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____ _____

गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"Comparative study of Modified Randall-Tennison's Repair and Fisher's Anatomical Subunit Repair in Unilateral Cleft Lip Patients" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ